UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT LABORATORIES,
Petitioner

IPR2025-00116
U.S. Patent No. 11,754,077

DECLARATION OF PETER CROSBY UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 11,754,077
1002	U.S. Patent No. 11,754,077 File History
1003	Declaration of Peter Crosby
1004	CV of Peter Crosby
1005	U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "*Rotary Pump Comprising a Hydraulically Mounted Motor*"
1006	Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, J Artif Organs 1999, Vol. 2, pp. 3-7
1007	Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor*, ASAIO Journal 2001
1008	U.S. Pat. Pub. No. US 2002/0102169A1 to Richard Wampler, et al., titled "*Sealless rotary blood pump*"
1009	Miracor's Supplemental Initial Response to Invalidity Contentions, dated September 20, 2024
1010	Frazier et al. *Total Heart Replacement with Dual Centrifugal Ventricual Assist Devices*, ASAIO Journal 2005
1011	Schob, *Centrifugal pump without bearings or seals*, World Pumps Vol. 2002, No. 430, pp. 34-37
1012	Rose et al., *Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure*, N Engl J Med. 2001 Nov 15, Vol. 345, No. 20, pp. 1435-43
1013	HeartMate® II LVAS: Patient Management Guidelines, December 14, 2006
1014	Schulman et al., *Comparisons of infection complications between continuous flow and pulsatile flow left ventricular assist devices,*

	The Journal of Thoracic and Cardiovascular Surgery 2007, Vol. 133, No. 3, pp. 841-842
1015	LaRose et al., *Heartware – A novel miniaturized passive maglev centrifugal VAD*, ASAIO Journal 2004 Mar, Vol. 50, No. 2, p. 137
1016	Qian et al., *Permanent magnetic-levitation of rotating impeller: a decisive breakthrough in the centrifugal pump*, Journal of Medical Engineering & Technology 2002 Jan/Feb, Vol. 26, No. 1, pp. 36-38
1017	Akamatsu et al., *Chronic Animal Experiment with Magnetically Suspended Centrifugal Pump*, Artificial Organs 1997, Vol. 21, No. 7, pp. 645-638
1018	U.S. Patent No. 6,050,975
1019	Exhibit 13 of Complaint, dated November 27, 2023
1020	Bottone et al., *Magnetos for automobilists, how made and how used*, Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/ magnetosforauto00bottgoog/page /n6/mode/2up)
1021	"Ignition magneto," accessed via https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024)
1022	Masuzawa et al. *Magnetically Suspended Centrifugal Blood Pump with an Axially Levitated Motor*, Artificial Organs 2003, Vol. 27, No. 7, pp. 631-638
1023	U.S. Patent No. 6,152,704
1024	U.S. Patent No. 6,589,030
1025	European Patent No. 0 834 326
1026	Miracor's Response to Exhibit F-1 (Bourque-2001) of Supplemental Invalidity Contentions, dated September 20, 2024
1027	U.S. Pat. No. 5,324,177
1028	Allaire, et al., *Prototype Continuous Flow Ventricular Assist Device*, J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690

1029	Kung and Hart, *Design Considerations for Bearingless Rotary Pumps*, J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650
1030	Declaration of Sylvia Hall-Ellis

I, Peter Crosby, do hereby declare as follows:

I. INTRODUCTION

1. I am making this declaration at the request of Petitioner in the matter of the *Inter Partes* Review of U.S. Patent No. 11,754,077 ("the 077 Patent") to Mohl et al.

2. I am being compensated for my work in this matter at my standard hourly rate. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this proceeding. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

3. I have been asked to provide my opinions regarding whether the subject matter of claims 1-5, 7, 10, 16-24, 26, and 28 ("the Challenged Claims") of the 077 Patent are anticipated or otherwise would have been obvious to a person having ordinary skill in the art ("POSITA") at the time of the alleged invention, in light of the prior art. It is my opinion that the Challenged Claims would have been obvious to a POSITA.

4. In the preparation of this declaration, I have studied:

a. the 077 Patent, Ex.1001.

b. the prosecution history of the 077 Patent ("077 File History"), Ex.1002.

c. U.S. Pat. Pub. No. US 2002/0102169A1 to Richard K. Wampler, titled "*Sealless Rotary Blood Pump*" ("Wampler-169"), Ex.1008.

d. Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor*, ASAIO Journal 2001 ("Bourque-2001"), Ex.1007.

e. Akamatsu et al., *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, J. Artif. Organs (1999) 2:3-7 ("Akamatsu-1999"), Ex.1006.

f. U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "*Rotary Pump Comprising a Hydraulically Mounted Motor*" ("Schima"), Ex.1005.

g. The additional references I refer to below and/or identified in the exhibit list.

5. In forming the opinions expressed below, I have considered: the documents listed above; the relevant legal standards as explained to me, including the standards for anticipation and obviousness; and my own knowledge and experience based upon my work in the field of network communications and security as described below.

6. Unless otherwise noted, all **emphasis** in any quoted material has been added. Claim terms are *italicized*. Exhibit titles are underlined.

II. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

7. My complete qualifications and professional experience are described in my *Curriculum Vitae*, a copy of which can be found in Ex.1004. The following is a brief summary of my relevant qualifications and professional experience.

8. I have over 45 years of experience in the medical device industry. I earned my Bachelor's degree in Electrical Engineering in 1974 and my Master's degree in Engineering Science in 1976, both from the University of Melbourne, Australia. My M.Eng.Sci. degree was in Biomedical Engineering, and I took courses and received training in advanced engineering, anatomy, and physiology as part of my M.Eng.Sci. work.

9. I am a named inventor of over 50 issued U.S. patents and public applications (and foreign equivalents). Most of my patents are in the general field of medical devices. Some of my patents are in the field of Left Ventricular Assist Devices (LVADs), the subject matter of the 077 Patent.

10. During my career I have worked as an engineer in research and development responsible for developing medical devices and have run the research and development function for several medical device companies. I spent

approximately 15 years in product research and development, including participation in design, engineering, manufacturing ramp-up, clinical trial design and execution, and regulatory submissions. Since then, I have spent most of my career in general management.

11. I have served as the Chief Executive Officer of six medical device companies in four countries, and as a member of the Board (including Chairman of the Board) of thirteen companies. In my career, I have brought over a dozen products from concept to market release, through research and development, manufacturing introduction, and clinical trials and regulatory approval in the United States as well as other markets worldwide, followed by development of a sales force and sales growth. I am keenly aware of the work and investment required to create a successful company in the medical device industry.

12. I have worked on the clinical trials and regulatory submissions for multiple products, starting in 1984 when I was the primary author of the Pre-Market Approval Application (PMAA) for Cochlear (a multi-channel implantable hearing prosthesis). I have developed clinical trial protocols, analyzed clinical data, and written or co-authored applications to the FDA for 510(k) clearance and Pre-Market Approval (PMA) in multiple fields.

13. I have worked in several clinical specialties, including cardiology and cardiac surgery, clinical pathology, medical software, otolaryngology, ophthalmology, intensive care, orthopedics, pain management, gastroenterology, medical imaging, and clinical education and training.

14. I have direct experience in the subject matter of the 077 Patent. From 2005, I worked for Ventracor, a company developing, manufacturing and marketing the VentrAssist Left Ventricular Assist Device (LVAD), and served as CEO from 2006 until 2009. The intellectual property assets of Ventracor were acquired by Thoratec in 2009, which was subsequently acquired by St. Jude Medical in 2015, which was subsequently acquired by Abbott in 2017. Those intellectual property assets are therefore now owned by the Petitioner. I have no financial interest in, and I do not receive a royalty or any other payment for any of those assets.

15. Earlier in my career, I was head of the Biomedical Engineering Department at a large metropolitan teaching hospital. Part of my responsibilities included support of all medical equipment in the hospital, including devices used in intensive care such as an Intra-Aortic Balloon Pump (IABP), part of the subject matter of the 077 Patent.

16. I currently work as a consultant, board member, and expert through my consulting business, Biomedical Business Resources, LLC. I am the Chairman of

the Board of two companies and a member of the Board of Directors of one other company.

III. LEVEL OF ORDINARY SKILL IN THE ART

17. I understand there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including (1) the levels of education and experience of persons working in the field at the time of the invention; (2) the sophistication of the technology; (3) the types of problems encountered in the field; and (4) the prior art solutions to those problems.

18. A Person of Ordinary Skill in The Art ("POSITA") as of the February 27, 2007 priority date of the 077 Patent would have: a) at least a bachelor's degree in engineering; b) knowledge and experience in the anatomy and physiology of the human circulatory system; and c) at least five years of experience in design and development of implantable medical devices.

19. For purposes of this Declaration, in general, and unless otherwise noted, my statements and opinions, such as those regarding my own experience and what a POSITA would have understood or known generally (and specifically related to the references I consulted herein), reflect the knowledge that existed in the relevant field as of the priority date of the 077 Patent.

IV. RELEVANT LEGAL STANDARDS

20. I am not an attorney. In preparing and expressing my opinions and considering the subject matter of the 077 Patent, I am relying on certain basic legal principles that counsel has explained to me.

21. I understand that prior art to the 077 Patent includes patents and printed publications in the relevant art that predate the priority date of the 077 Patent. For purposes of this Declaration, I am applying February 27, 2007, as the priority date of the 077 Patent, but I take no position on that issue.

22. I have been informed by counsel that a claimed invention is invalid if it is "anticipated" by the prior art. I understand that, for a patent claim to be "anticipated" by the prior art, each and every requirement of the claim must be found, expressly or inherently, in a single prior art reference as recited in the claim. I understand that claim limitations that are not expressly described in a prior art reference may still be there if they are "inherent" to the thing or process being described in the prior art.

23. I understand that if a reference incorporates other documents by reference, the incorporating reference and the incorporated reference(s) should be treated as a single prior art reference for purposes of analyzing anticipation.

24. I understand that it is acceptable to consider evidence other than the information in a particular prior art document to determine if a feature is necessarily present in or inherently described by that reference.

25. I have been informed by counsel that a claimed invention is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a POSITA. I have also been informed by counsel that the obviousness analysis considers factual inquiries, including the level of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

26. I have been further informed by counsel that there are several recognized rationales for combining references or modifying a reference to show obviousness. These rationales include: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of a known technique to improve a similar device (method, or product) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (f) some teaching,

suggestion, or motivation in the prior art that would have led a POSITA to modify the prior art or to combine prior art teachings to arrive at the claimed invention.

V. OVERVIEW OF THE 077 PATENT

27. The 077 Patent states that it is a continuation of and claims priority to U.S. application Ser. No. 18/087,083 filed on Dec. 22, 2022, which is a continuation of and claims priority to U.S. application Ser. No. 17/446,046 filed on Aug. 26, 2021 (now U.S. Pat. No. 11,572,879), which is a continuation of U.S. application Ser. No. 16/282,948 filed on Feb. 22, 2019 (now U.S. Pat. No. 11,123,540), which is a continuation of U.S. application Ser. No. 14/454,965 filed on Aug. 8, 2014 (now U.S. Pat. No. 10,251,984), which is a continuation of U.S. application Ser. No. 13/555,318 filed on Jul. 23, 2012 (now U.S. Pat. No. 8,801,590), which is a divisional of U.S. application Ser. No. 12/449,632 filed on Aug. 18, 2009 (now U.S. Pat. No. 8,255,050), which is the U.S. national phase of International Application PCT/IB2008/000421 filed on Feb. 27, 2008, which designated the U.S. and claims benefit of AT A 306/2007 filed Feb. 27, 2007. Ex.1001, 1:7-23.

28. I have been asked to assume that **February 27, 2007** is the effective filing date, but I take no position on that issue.

29. I have reviewed the file history of the 077 Patent, including that of the aforementioned U.S. and International Patents, to which the 077 Patent claims priority, and note that none of the activity there is pertinent to my analysis.

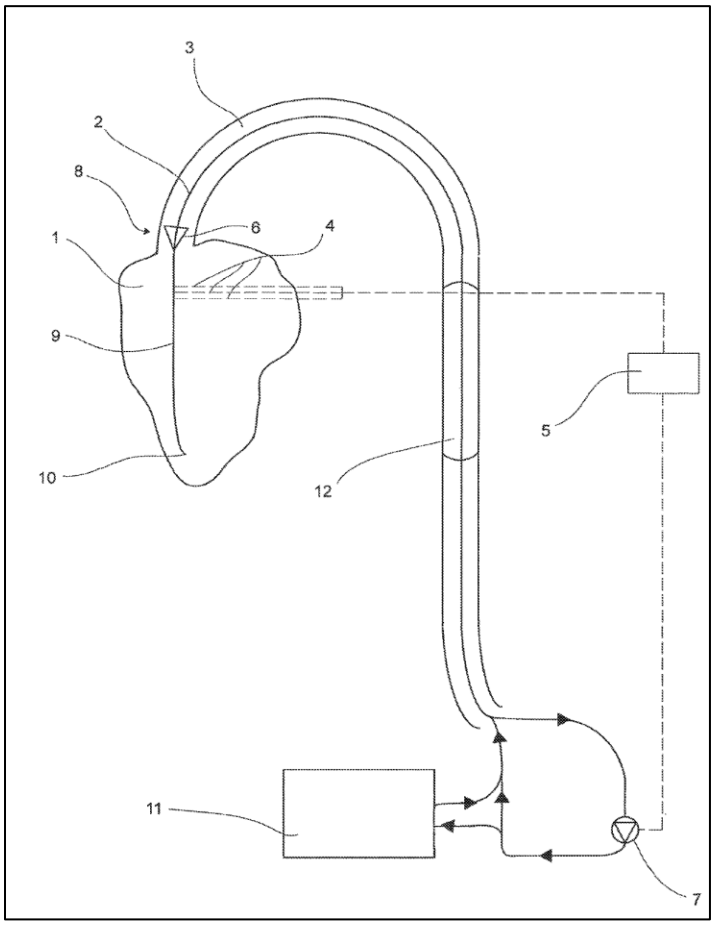
A. The 077 Patent's specification is generally directed to a catheter device.

30. The 077 Patent's specification is generally directed to a catheter device (and method of using the device) for assisting blood flow in the heart, which purports to improve upon conventional heart-lung machines that used external pumps to maintain a forced circulation of blood without entering the heart. Ex.1001, 2:19-62 (describing "the embodiment to assist the performance of a heart according to the invention" which has a pump "formed…at the distal end of the catheter" and a rotor with a drive that "is arranged inside the catheter"). The 077 Patent seeks to improve on a known device in which "fluid is removed from the blood vessels via an external pump and returned into blood vessels via a return catheter." Ex.1001, 1:63-2:2.

31. According to the specification, the invention sought to improve the fluid flow provided by the pump in a way in which the mechanical stress on the blood is kept low, while circulation is ensured at desired locations. Ex.1001, 2:19-23. The 077 Patent purports to solve that problem with a pump "formed as an intravasal rotary pump at the periphery or at the distal end of the catheter, the rotor

of which, lying on the outside, is connected via a magneto coupling with the drive which is arranged inside the catheter." Ex.1001, 2:52-62.

32. Figure 1 of the 077 Patent shows the overall configuration and is reproduced below:



Ex.1001, Fig. 1.

33. As shown in Figure 1 of the 077 Patent, "heart ventricle catheter 2" is introduced to a "heart 1" for example "via the femoral artery and the aortic arch 3 into the heart chamber and carries a series of sensors 4 via which the volume can be

determined. The measurement signals are passed to a control arrangement 5." Ex.1001, 3:10-15. The heart ventricle catheter 2 is formed with "several lumina" which supply fluid to drive a rotor 6 "arranged at the distal end, which forms the pump to assist the blood circulation." Ex.1001, 3:15-20. A "fluid pump 7" is used as the driving medium for the rotor and is regulated "as a function of the control signals generated in the control arrangement 5." Ex.1001, 3:23-26. The catheter 2 has "at its distal end a tube 9 leading to the suction end 10." Ex.1001, 3:26-29.

34. The 077 Patent does not specify what the "driving fluid" is but a POSITA would understand it to refer to either a liquid or gas as the described paddle wheel is operated "hydraulically or pneumatically." Ex.1001, 3:29-33, Claim 6. A POSITA would understand that "pneumatic" drive would be limited to a small number of gases (e.g., helium) because of the risk of gas embolism in the case of rupture or breakage of any element of the system. A POSITA would also understand that "hydraulic" drive is limited to a small number of fluids, of which isotonic saline is typically the most appropriate. Blood cannot be used as a driving fluid because it would coagulate in the hydraulic reservoir.

35. Figure 2 depicts an embodiment of the catheter 2 described in the 077 Patent, and is reproduced below:

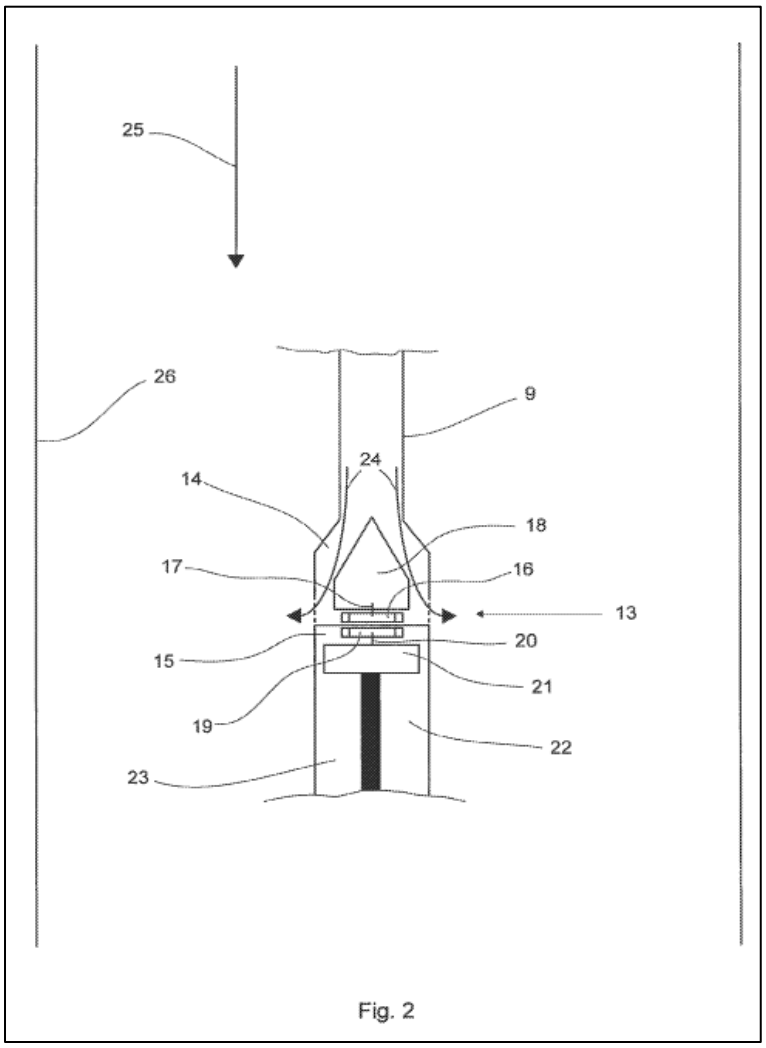


Fig. 2

Ex.1001, Fig. 2.

36. Figure 2 illustrates that the end side 13 of the catheter "has two pocketshaped chambers 14 and 15, in which bar magnets are respectively arranged." Ex.1001, 3:50-53. In the chamber 14, the "bar magnet 16" is connected at the "distal end outwards via a shaft 17 with a rotor 18." Ex.1001, 3:53-56. In chamber 15, "bar magnet 19" lies on the inside "connected via a shaft 20 with a drive wheel 21."

Ex.1001, 3:53-56. The drive wheel 21 is formed as a "paddle wheel 21" that is acted upon with fluid via lumen 22, which flows off again via lumen 23. Ex.1001, 3:56-59. Lumen 22 and lumen 23 of the catheter, each located in chamber 15, are completely sealed from chamber 14. Ex.1001, Fig. 2, 3:64-65. The rotation of the paddle wheel 21 is regulated by "corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which the magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation." Ex.1001, 3:59-64. As a result of the rotation of magnet 19 in chamber 15, magnet 16 in chamber 14 is caused to rotate accordingly and "drives the rotor 18 via the shaft 17, whereby a flow is formed in the region of the tube 9." Ex.1001, 3:65-4:3.

B. The 077 Patent's specification describes that its rotor design was already disclosed in the prior art.

37. The 077 Patent's specification describes:

> The rotor itself can follow design principles such as described for example in WO 01/70300 A1. The rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is not directly suitable for incorporation into a catheter.

Ex.1001, 2:29-34. This statement—that the rotor "can follow design principles" from the prior art—supports my views outlined in the grounds below that there was nothing novel disclosed in the 077 Patent's specification about the design of the rotor.

38. As I explain below in connection with "Schima" (Ex.1005) which is a related publication to WO 01/70300 Al, I understand that in parallel litigation, the Patent Owner argues that WO 01/70300 Al would have enabled a POSITA to practice the full scope of the claimed invention without undue experimentation. Ex.1009, Miracor's Supp. Initial Response to Invalidity Contentions at 7 ("Defendants recite…that the specification does not enable a POSITA to practice the full scope of the claimed invention without undue experimentation. However, this cited excerpt refers to known design principles for a rotor as described in WO 01/70300 Al.") (internal quotation marks omitted). This statement in the specification and concession from Patent Owner confirms my opinion that the 077 Patent's specification does not disclose anything novel about rotor designs for devices to assist the performance of a heart, because such designs were already disclosed, *e.g.*, by Schima.

39. Further, as discussed below, the use of magnetic components in a heart assist pump device to drive the flow of blood while reducing mechanical stress on such components was well-known in the art at the time of the purported invention.

VI. BACKGROUND OF THE TECHNOLOGY ACCUSED OF INFRINGEMENT IN THE PARALLEL LITIGATION

40. As I described above, the 077 Patent's specification is directed to a catheter device. In the parallel litigation, however, I understand that the Patent Owner has accused of infringement Abbott's HeartMate 3 LVAD, which is not a catheter device. Thus, I provide below a summary of the development of LVAD devices, such as the HeartMate 3 accused of infringement, and the types of bearings that can be used in an LVAD.

A. Historical development of LVAD Devices.

41. It was widely recognized prior to February 2007 that "[c]ongestive heart failure (CHF) [was] an important and increasing cause of cardiovascular disability and premature death in the United States." Ex.1010 (Frazier 2005) at 224. For example, as of 2001, "[e]ach year in the United States, 400,000 people [were] diagnosed with congestive heart failure (CHF)." Ex.1007 (Bourque-2001) at 401. Driven by a growing need for heart failure treatment options to address these problems and the limited availability of donor heart transplants, researchers began

designing and developing left ventricular assist devices (LVADs) in the 1990s, which assist in circulating blood from the left ventricle of a patient's heart to the aorta. Ex.1007 (Bourque-2001) at 401; Ex.1010 (Frazier 2005) at 224.

42. The terms Left Ventricular Assist System (LVAS) and Left Ventricular Assist Device (LVAD) are synonymous. An LVAS consists of several main elements: a) an inflow cannula (tube, or conduit) placed with its opening in the left ventricle of the heart; b) the pump itself; c) an outflow cannula from the pump to the circulatory system, typically to the aortic root; d) a system to provide power and control to the pump; and e) a power source (typically a body worn battery pack).

1. Disadvantages of early-generation LVADs included mechanical bearings and increased risk of infection associated with their large size.

43. First-generation LVADs were pulsatile devices, such as the HeartMate XVE, and while effective, "contain[ed] mechanical parts that wear, such as ball bearings, flexible diaphragms or sacs, and valves." Ex. 1007 (Bourque-2001) at 401. Further, "[b]iological fluids like blood get destroyed in the bearing and tend to clot." Ex.1011 (Schob 2002) at 1.

44. A disadvantage of these first-generation devices is that because of their larger size they were "implanted into a preperitoneal pocket" in the patient:

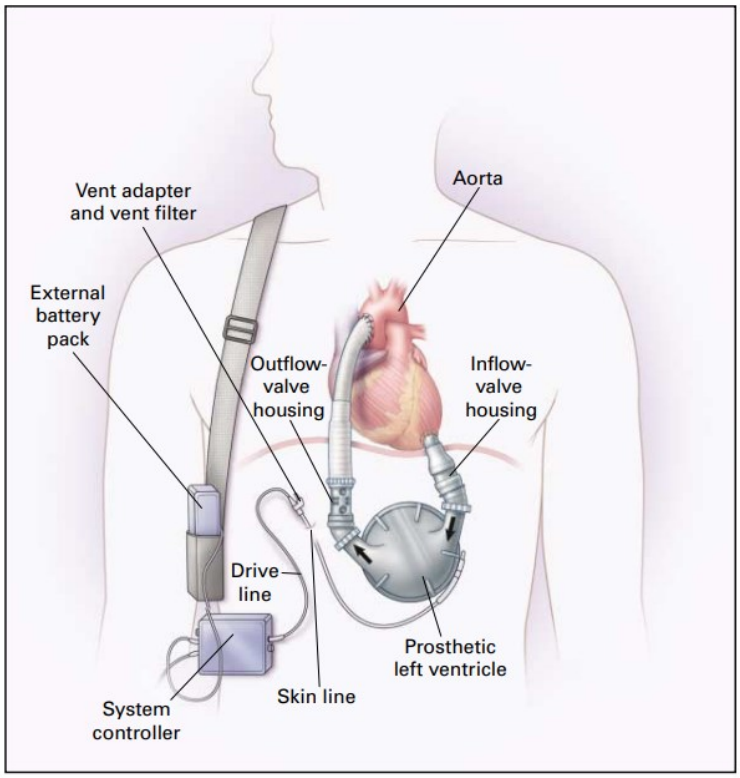


Figure 1. Components of the Left Ventricular Assist Device.
The inflow cannula is inserted into the apex of the left ventricle, and the outflow cannula is anastomosed to the ascending aorta. Blood returns from the lungs to the left side of the heart and exits through the left ventricular apex and across an inflow valve into the prosthetic pumping chamber. Blood is then actively pumped through an outflow valve into the ascending aorta. The pumping chamber is placed within the abdominal wall or peritoneal cavity. A percutaneous drive line carries the electrical cable and air vent to the battery packs (only the pack on the right side is shown) and electronic controls, which are worn on a shoulder holster and belt, respectively.

Ex.1012 (Rose 2001), Fig. 1, 1436.

45. The larger size of these devices required "surgical dissection" to place the device in a "pump pocket," which was associated with increased risk of infection. Ex.1014 (Schulman 2007) at 842. One clinical study reported that "[w]ithin three months after implantation, the probability of infection of the left ventricular assist device was 28 percent" and that the infection of the pocket was the most commonly reported type of infection. Ex.1012, Table 5. The "morbidity and mortality

associated with the…infection…were major factors in the two-year survival rate of only 23 percent." Ex.1012 at 1441. The "increased rates of adverse events" signaled a "need for further improvements in…the design of the device." Ex.1012 at 1442.

46. Recognizing these problems, by the early 2000s researchers in the industry "ha[d] focused their efforts on continuous flow-type pumps (*e.g.*, HeartMate II, Thoratec Corp.) for the second generation of LVADs to exploit inherently fewer mechanical parts and many additional benefits such as smaller size and lower cost." Ex.1007 (Bourque-2001) at 401. Unlike the first-generation pulsatile devices, the later generation devices were "continuous flow-type" pumps, which are rotating pumps (axial flow or centrifugal flow), and therefore their implementation needed to address the engineering problems created by the use of bearings and the supply of torque. Ex.1007 at 401. That is, the so-called "second-generation" pumps were rotating pumps with mechanical bearings (albeit, fewer mechanical bearings) that supported the rotating part of the pump. Ex.1007 at 401.

47. Like the first-generation devices, the second-generation devices (e.g., the HeartMate II) were also typically implanted into a preperitoneal pocket in the patient.

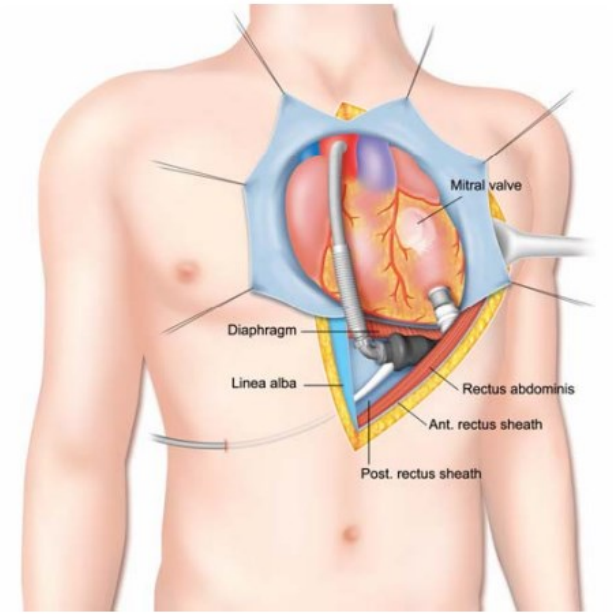


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

See, e.g., Ex.1013 (HeartMate® II LVAS: Patient Management Guidelines) at 25. For instance, "[a]s with preperitoneal placement of the HeartMate XVE device, preperitoneal placement of the HeartMate II requires the dissection of a pocket." Ex.1013 at 25.

48. Because the second-generation devices were "smaller" "and d[id] not require a great deal of surgical dissection," they had a "low[er] infection rate" compared to the earlier devices. Ex.1014 at 842. It was well understood that the "[d]ifferences in infection rates between [first-generation] pulsatile and [second-

generation] continuous flow LVADs [were] a reflection of differences in device design." Ex.1014 at 842.

49. Although better than the first-generation devices, the pump pocket dissection was still considered a disadvantage. For example, it was recognized that although "the pocket dissection is smaller with the HeartMate II [second-generation device],…potentially introducing less risk of infection" than the larger pockets required for the first-generation devices, the "preperitoneal pocket position" was still considered a "disadvantage[]" due to the "increased risk of infection" and "[p]otential for prolonged pocket drainage." Ex.1013 at 25-26.

2. Third-generation LVADs aimed to eliminate mechanical bearings.

50. The third-generation of LVADs sought "to feature the advantageous qualities of such second generation pumps" "such as smaller size" "while carrying expected device life one step further [by eliminating] mechanical bearings." Ex.1007 at 401.

51. Eliminating mechanical bearings was achieved by "magnetic levitation technology." The aim to eliminate mechanical bearings altogether in these so-called "third-generation pumps" began in the late 1990s and early 2000s. Ex.1007 at 401; Ex.1008 (Wampler-169), [0003]-[0005]. It was recognized that this could be

accomplished by the use of centrifugal pumps with "magnetic levitation technology." Ex.1007 at 401; Ex.1008, [0003]-[0005]; Ex.1006 at 3; Ex.1011 (Schob 2002) at 34. "Major problem[s]" existed with previous centrifugal pumps delivering sterile or delicate fluids (e.g., blood), such as "mechanical seal failures" and "failure of bearings, couplings and other associated items" that result in costly maintenance and shorten the operable lifespan of the pump. Ex.1011 at 1. It was widely recognized, however, that "[a]ll these problems [could] be addressed by magnetic levitation technology." Ex.1011 at 1. For example, the HeartMate III as described in Bourque-2001 features "a centrifugal pump with a magnetically levitated rotor" and "[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401.

52. Smaller size was also achieved. For example, the HVAD, another third-generation type device, reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch, thus, [t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for intrapericardial pump placement and fast implantation." Ex.1015 (LaRose).

a. Two types of drives existed for third-generation devices.

53. The impeller (or rotor) of third-generation pumps could be driven in at least two different ways—by "magnetic coupling" or by "magnetic levitation" technology. Ex.1011 (Schob 2002) at 1. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described for example in Bourque-2001. Ex.1007 at Abstract.

54. "In the magnetic coupling pump [a] rotating [magnetic] field is generated by rotating magnets" so that "torque is transmitted through the canning onto the rotor by means of [the] rotating magnetic field." Ex.1011 at 1. Said another way, an "impeller is fixed on one side of [a] rotor; on the other side…rotor magnets are mounted. Opposite these rotor magnets, a driving magnet is fastened to the motor axis. Thereafter, the motor drives the rotor via **magnetic coupling**." Ex.1016 (Qian) at 36. Figure 2 of "Akamatsu-1999" (Ex.1006) illustrates a schematic cross section of a centrifugal pump using magnetic coupling:

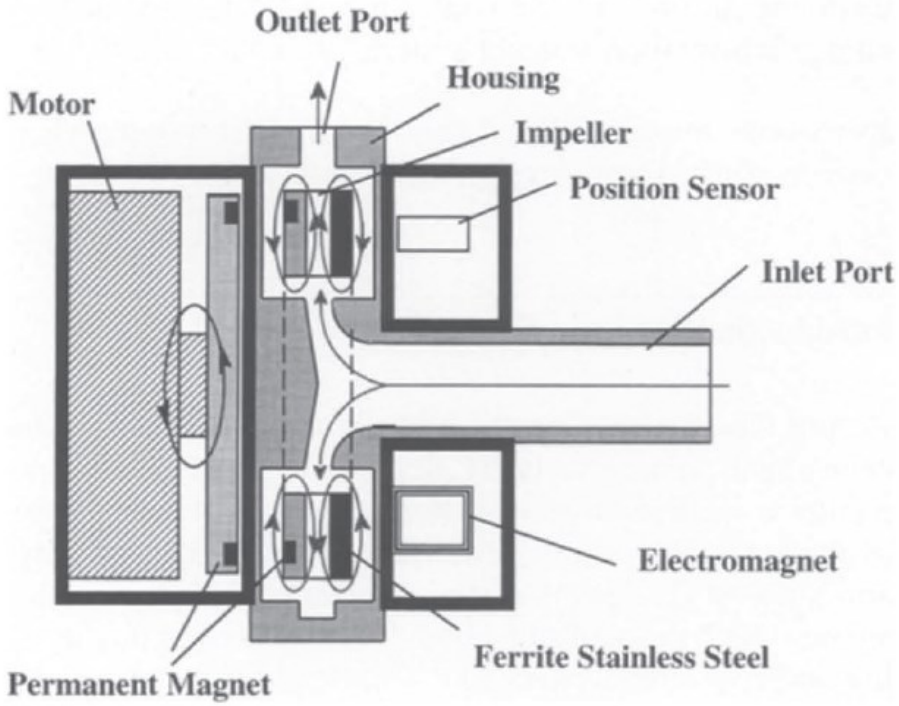


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

55. Put simply, "magnetic coupling" uses a motor to rotate a permanent magnet, which in turn rotates another permanent magnet on the impeller.

56. "Magnetic levitation" design, however, uses a stationary electric motor to produce a rotating magnetic field (as opposed to rotating a permanent magnetic to produce a rotating magnetic field). These designs use "a single motor/bearing unit that provides drive and magnetic bearing functions at one and the same time." Ex.1011 at 1-2; Ex.1011, Figure 1 ("Schematic showing the basic principles" of the

magnetic levitation design). Figure 4 of Bourque-2001 (Ex.1007) illustrates a schematic cross section of a centrifugal pump using magnetic levitation drive.

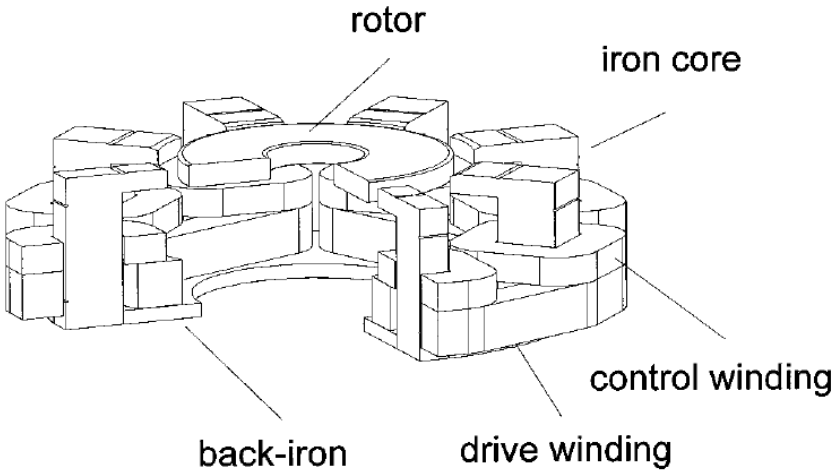


Figure 4. HeartMate III motor, drive, and levitation (control) in a single magnetic structure.

Ex.1007 at 402 (Fig. 4).

b. Two types of bearings existed for third generation devices.

57. To replace the mechanical bearings of past generation devices, third-generation LVADs devices generally used a hydrodynamic bearing or a magnetic bearing (or a hybrid of the two) to suspend the impeller.

58. Mechanical bearings rely on physical contact between components to stabilize a rotor in the housing during rotation.

59. A "hydrodynamic bearing" (also known as a fluid bearing), which was a well-known and commonly used term in the art when the 077 Patent was filed,

uses motion to create a pressure that forces a rotating component, such as a rotor, apart from a surface by a fluid flowing between the rotating component and the surface. *See, e.g.,* Ex.1008 (Wampler-169), [0092]. The stationary surface (here, the pump housing) and rotating surface (here, the rotor) are separated by a thin film of fluid (here, blood) when the rotor is in rotation. The film pressure that separates the surfaces is created by the relative motion (rotation) of the surfaces as the lubricant is pulled into a converging geometry between the surfaces. As Qian describes it, there is a "'taking off' of the rotor [that] is generated by a hydraulic force (a reacting force of the flow), which acts on the impeller because the impeller propels the flow." Ex.1016 at 37, abstract ("the axial levitation is produced by hydraulic force").

60. Magnetic (or "electromagnetic") bearings, such as described in Bourque-2001 for the HeartMate III device (*infra* §IX.B), use electromagnets to levitate a rotor without physical contact:

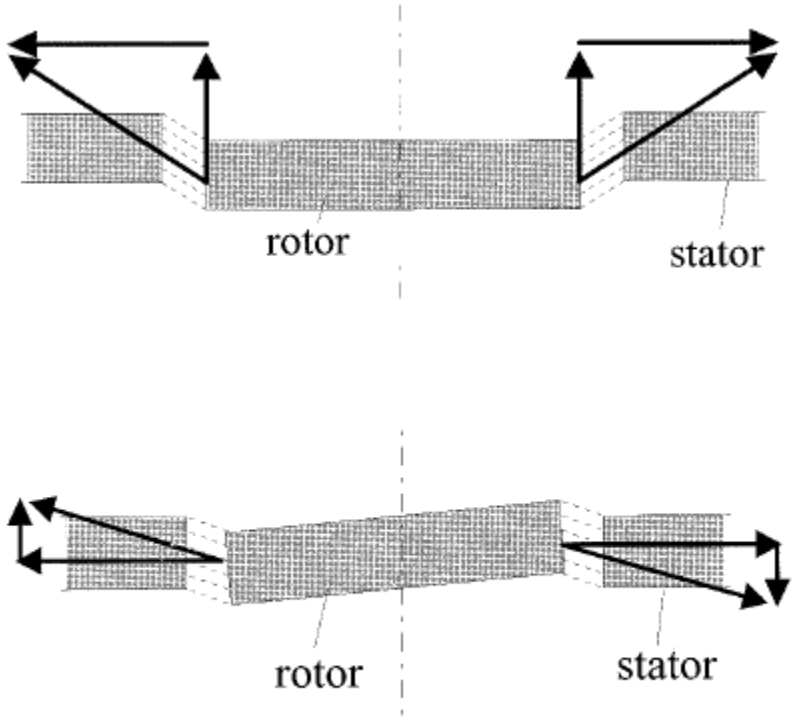


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007 at 404 (Fig. 5); Ex.1016 (Qian) at 36 ("Some investigators have developed magnetic bearings with electromagnets [citing *Heartmate III: bearingless motor design for a maglev centrifugal LVAD*], achieving zero friction and no contact between rotor and stator. This results in no mechanical wear.").

c. The smaller third-generation devices could be placed at the cardiac apex within the pericardial space.

61. The smaller size of third-generation devices enabled these devices to be placed at the cardiac apex within the pericardial space instead of dissecting a

preperitoneal pocket, which was associated with infection in the earlier generation devices.

62. For example, Wampler-169 reported that "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm:":

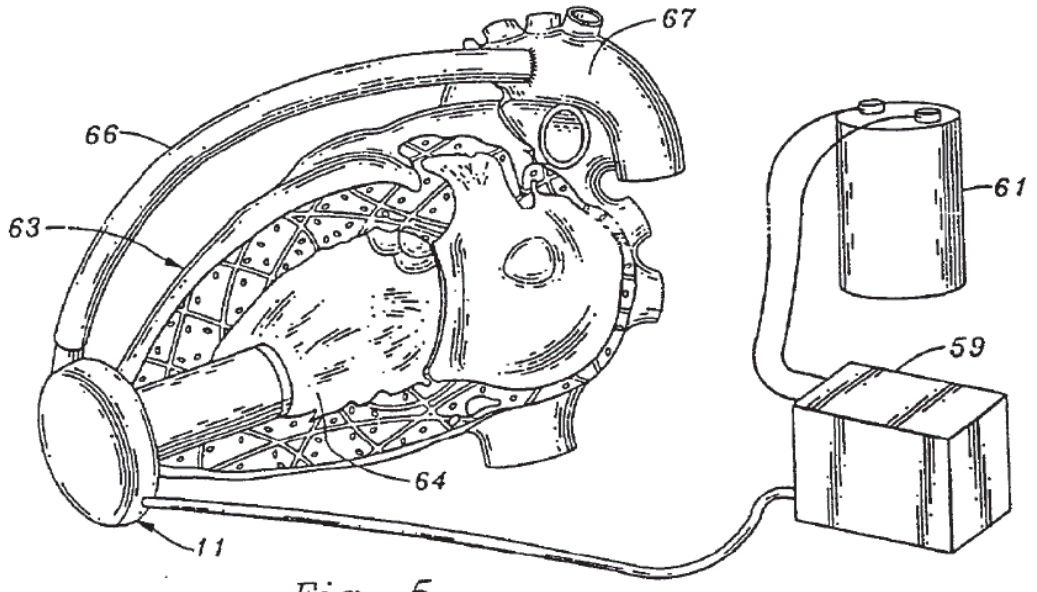


Fig. 5

Ex.1008, [0076], Fig. 5. When placed at the cardiac apex, an inlet tube and is placed into the apex of the left ventricle. Ex.1008, [0075]-[0076].

63. As another similar example, the HVAD reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch," thus, "[t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for

intrapericardial pump placement and fast implantation." Ex.1015 (LaRose). As yet another example, one of "[t]he advantages of the [Akamatsu-1999] rotary blood pump [is] its compactness" that allows it to be implanted in patients at the cardiac apex "even those of small body size." Ex.1006 at 3.

64. The Bourque-2001 HeartMate III was "implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta" of the test models and could be placed at the preperitoneal pocket as shown:

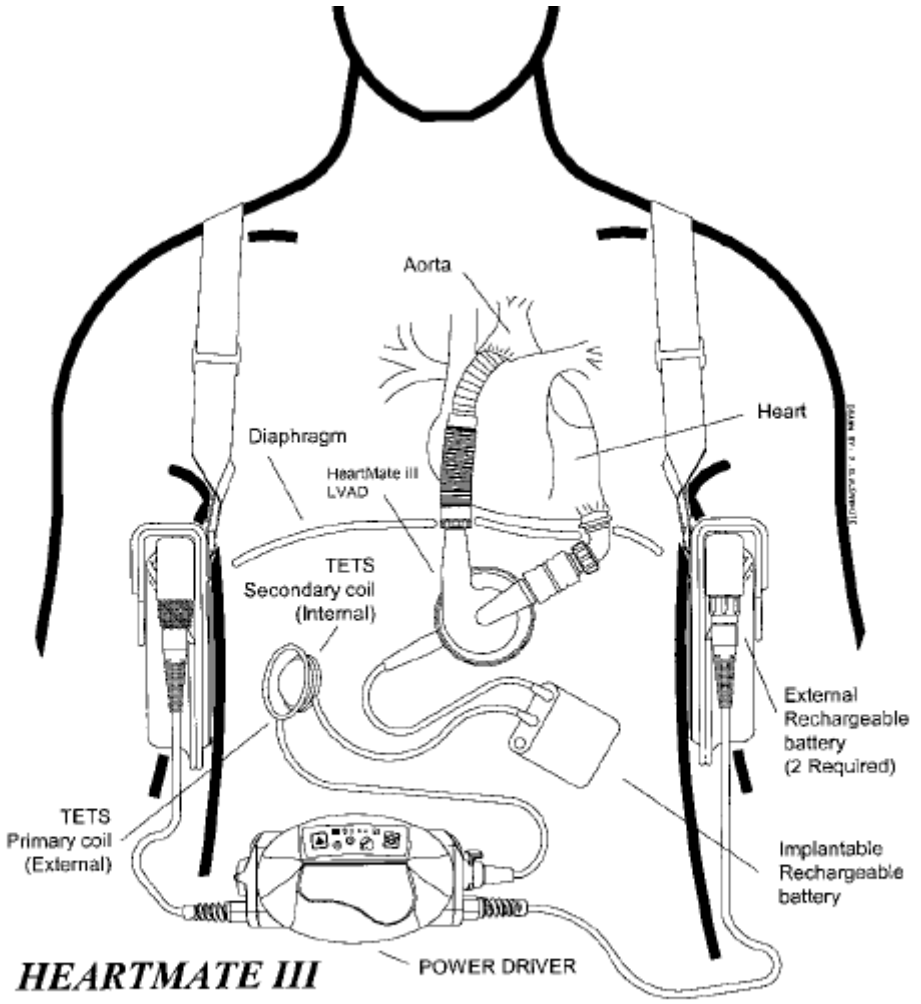


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3, 403. However, the Bourque-2001 HeartMate III was already planned for "enhancements [to] continue the progression of this LVAD's development as a compact" device, which would enable its placement at the cardiac apex as discussed below. Ex.1007, at 405.

65. As will be discussed further with respect to the Grounds below, the concept and design of the HeartMate III (now referred to as the "HeartMate 3") accused of infringement in the parallel litigation, and specifically, the use of magnetically driven rotors for use in LVAD heart pumps for the treatment of heart failure, was already well-known in the prior art. Section IX.B.

VII. CLAIM CONSTRUCTION

66. It is my understanding that to properly evaluate the 077 Patent, the terms of the claims must first be interpreted. It is my understanding that for the purposes of this *inter partes* review, the claims are to be construed under the so-called *Phillips* standard, under which claim terms are given their ordinary and customary meaning as would have been understood by a POSITA in light of the specification and prosecution history, unless the inventor has set forth a special meaning for a term. I have also been informed that claim terms only need to be construed to the extent necessary to resolve the unpatentability inquiry.

A. Plain and Ordinary Meaning of Certain Claim Terms

67. I have reviewed the Patent Owner's complaint served in the parallel litigation, and the Patent Owner's apparent construction of two claim terms significantly differs from those terms' plain and ordinary meanings. The challenged

claims, however, are unpatentable under any interpretation, thus, in my opinion, the claim terms need not be expressly construed.

1. "magneto coupling" (Claim 11)

68. In my opinion, a POSITA as of February 27, 2007, would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating permanent magnetic component to another rotating permanent magnetic component via a magnetic field." As I discussed above, "magneto coupling" drive differs from, for example, "magnetic levitation" drive.

69. As a preliminary matter, I note that a POSITA would understand that the term "magnet**o** coupling," when read in view of the 077 Patent's specification, refers to the concept of "magnet**ic** coupling" between two permanent magnets, as described in further detail in the prior art below. In my experience, the term "magnet**o** coupling" is not generally used in the field of rotary pump devices. A "magneto" is a traditional type of electrical generator that uses permanent magnets to produce pulses of electricity, and which was a well-known device in other fields of art as of February 2007.[10] For example, from my own experience, a magneto is a

[10] *See, e.g.*, Ex.1020, Bottone et al., *Magnetos for automobilists, how made and how used*, Crosby Lockwood and Son, Ch. 1 (1907) (accessed at https://archive.org/details/magnetosforauto00bottgoog/page/n6/mode/2up).

technology over 100 years old used in ignition systems, such as reciprocating aircraft engines to provide the high voltage to the spark plugs for ignition.[11] The 077 Patent's specification includes no discussion of a "magneto" device, nor is the "magneto coupling" recited in the claims directed to the functionality of a traditional "magneto." The specification refers instead to a "bar magnet" driven in rotation via a coupling with a rotating second "bar magnet," which corresponds to the type "magnet**ic** coupling" between permanent magnets in rotary pump systems that was known in the art. Ex.1001, 3:50-4:3.[12] Thus, for the purposes of my analysis, I interpret the plain and ordinary meaning of "magneto coupling," as used in the 077 Patent's specification to refer to the same concept as "magnetic coupling." The term does not refer to "electromagnetic coupling" which I interpret as a rotating magnetic

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[11] *See, e.g.*, Ex.1021, "Ignition magneto," accessed at https://en.wikipedia.org/wiki/Ignition_magneto (last accessed October 28, 2024).

[12] I note that the word "magneto" is also used in the specification in the context that the "lumina for the driving fluid" have "controllable closure members via which driving fluid can arrive in the balloon or out of the balloon into the respective lumina, in which preferably the closure members are formed as ***magneto valves***." Ex.1001, 2:42-48. As with the term "magneto coupling," the term "magneto valve" is also not generally used in the field of rotary pump devices. However, "magnet**ic** valves" were well known components in mechanical systems that use magnetism to move a plunger within the valve to regulate flow. Thus, this additional usage of "magneto" further supports my understanding that the specification refers to "magneto coupling" as the same concept as "magnetic coupling."

field produced by a stationary electromagnet coupled to one or more permanent magnets in the rotated device.

70. Accordingly, "magneto coupling" (i.e., magnet**ic** coupling) was a commonly used and understood term in the art as of the priority date of the 077 Patent, and it was understood to refer to exactly this type of non-contact transfer of energy used in a mechanical system to transfer torque from one rotating permanent magnet to another rotating permanent magnet via a magnetic field.

a. The specification and prior art consistently distinguish magnetic coupling from other types of drive.

71. As noted, my understanding is also consistent with the use of the term in the 077 Patent's specification. For example, the 077 Patent explicitly identifies "magneto coupling" as referring to a transfer of torque between two magnetic components—a "bar magnet 16" connected "at the distal end outwards via a shaft 17 with a rotor 18" and a "bar magnet 19 lying on the inside…connected via a shaft 20 with a drive wheel 21."[13] Ex.1001, 3:53-56. Specifically, the 077 Patent explains that "the rotor lying distally on the outside is coupled via a magneto coupling with a drive wheel." Ex.1001, 2:60-62. It is the *rotation* of the first magnetic component

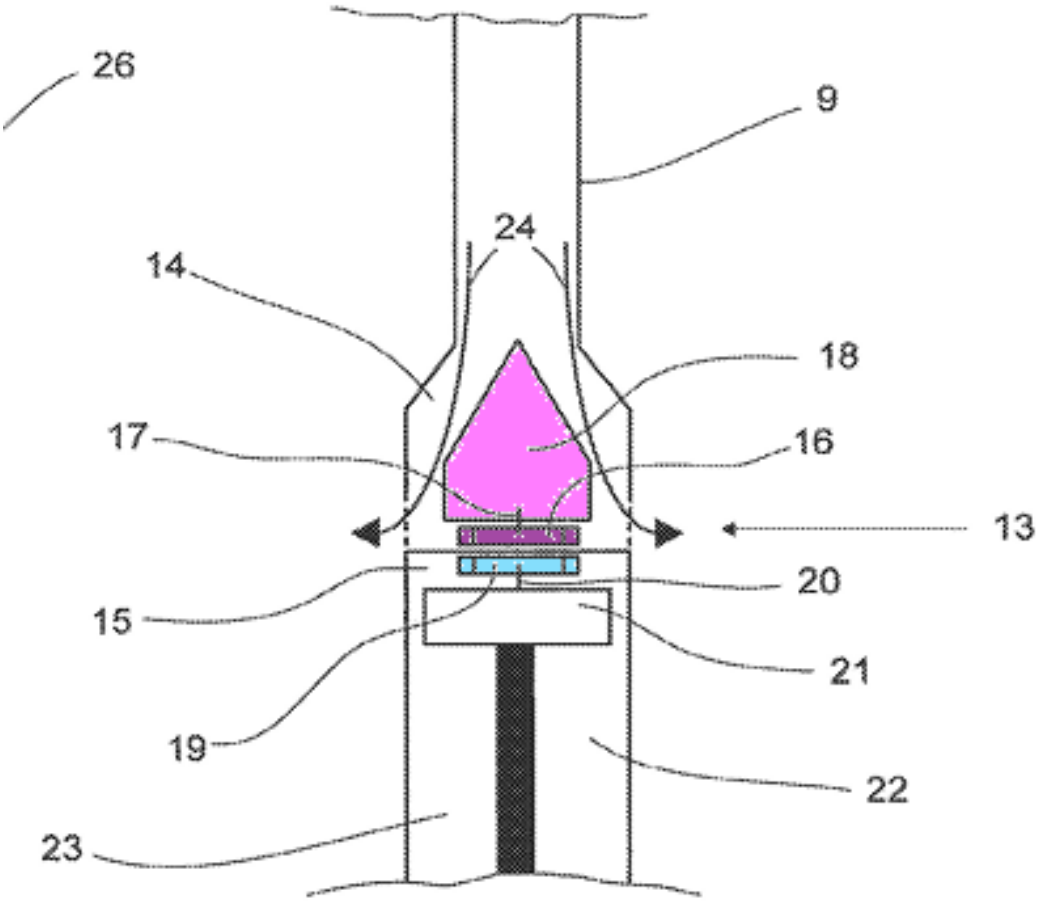
[13] I note that a "bar" magnet was a commonly used type of permanent magnet as of the February 2007 priority date.

(bar magnet 19) that causes the rotation of the rotor by the magneto coupling with the second magnetic component (bar magnet 16):

> The rotation of the paddle wheel 21 is regulated here accordingly by corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which the [rotor] magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation.

Ex.1001, 3:59-64.

72. Figure 2 (annotated and enlarged for illustrative purposes) of the 077 Patent, shows the "bar magnet 19" (**light blue**), which when locked in relative rotation with the paddle wheel 21 via shaft 20, transfers torque to "bar magnet 16" (**purple**), which drives rotation of the "rotor 18" (**pink**):



Ex.1001, Fig. 2 (annotated).

73. This plain and ordinary meaning is also consistent with the use of the term in the art as of February 27, 2007. Further, the art distinguishes rotation by magneto coupling from, for example, rotation caused by an electromagnetic field induced by an electric current (e.g., drive by magnetic levitation).

74. For example, Schob 2002 (Ex.1011) describes and distinguishes "magnetic coupling" pumps from pumps that are driven by "magnetic levitation."

Schob 2002 states that "[i]n the magnetic coupling pump [a] rotating [magnetic] field is generated by rotating magnets" so that "torque is transmitted through the canning onto the rotor by means of [the] rotating magnetic field." Ex.1011 at 1. "Magnetic levitation" design, however, has a single motor/bearing unit that provides drive and magnetic bearing functions at one and the same time." Ex.1011 at 1-2.

75. Qian (Ex.1016) provides similar descriptions, stating that "magnetic coupling" refers to a "motor [that] drives the rotor via magnetic coupling" by "using only permanent magnets." Ex.1016 at 37. Qian further describes that "[t]he magnetic coupling transmits the rotating torque from the motor to the pump" where "driving magnets and…driven magnets attract each other" so "that the two magnet assemblages will stay concentric with each other." Ex.1016 at 37; *see also* Ex.1016 at abstract ("The impeller is fixed on one side of the rotor; on the other side the rotor magnets are mounted. Opposite these rotor magnets, a driving magnet is fastened to the motor axis. Thereafter, the motor drives the rotor via **magnetic coupling.**").

76. Qian also distinguishes magnetic coupling devices from devices like the Heartmate III, which use magnetic levitation for drive. Ex.1016 at 36 ("Some investigators have developed magnetic bearings with electromagnets [citing *Heartmate III: bearingless motor design for a maglev centrifugal LVAD*]….the authors have developed a levitated impeller pump using only permanent magnets.").

The fact that Qian distinguishes "magnetic coupling" using permanent magnets from the type of drive used by the Heartmate III, which uses magnetic levitation by a rotating electromagnetic field, supports my opinion that the plain and ordinary meaning of "magneto coupling" refers to a transfer of torque from one rotating permanent magnet to another rotating permanent magnet.

77. Similarly, Masuzawa (Ex.1022) describes that "a magnetic coupling mechanism to rotate [a] levitated rotor" includes "[a] motor with bearings…used to rotate permanent magnets that transfer torque to the rotor." Ex.1022 at 631. Further, Masuzawa distinguishes magnetic coupling (i.e., the mechanism used in the DuraHeart developed by Terumo) from the use of an electromagnet (i.e., the mechanism used in the HeartMate III developed by Thoratec):

> Magnetic suspension techniques have been used to eliminate the mechanical parts of centrifugal blood pumps (1–6). In particular, a group at Kyoto University introduced an axial-type magnetically suspended centrifugal pump as a ventricular assist device—the DuraHeart, currently developed by Terumo Corp.—and demonstrated survival of over 1 year in animal experiments. However, **that device uses a magnetic coupling mechanism** to rotate the levitated rotor. A motor with bearings, which limits the lifetime of the device, is used **to rotate permanent magnets that transfer torque to the rotor**. The HeartMate III developed by Thoratec Corp. uses a radially suspended self-bearing motor whose smaller diameter inner rotor helps to miniaturize the pump.

Ex.1022 at 631. The fact that Masuzawa describes magnetic coupling as a mechanism that uses rotating permanent magnets to transfer torque to the rotor, and the fact that Masuzawa distinguishes magnetic coupling from the magnetic levitation drive used in the HeartMate III device (which uses electromagnets) support my opinion on this term's plain and ordinary meaning.

78. Likewise, Aboul-Hosn (U.S. Patent No. 6,152,704; Ex.1023) similarly uses "magnetic coupling" to describe transmitting rotation from one rotating permanent magnet to another. For example, Aboul-Hosn discloses a blood pump where "[t]he pump snaps onto [a] turbine drive unit and a magnetic coupling between the pump and the drive unit is used to transmit the rotation of a turbine shaft to the pump impeller." Ex.1023 at abstract; *see also* Ex.1023 at 2:54-57 ("The disk-shaped member 34 and magnets 36 provide one half of the magnetic coupling for transmitting rotation from the turbine drive unit 12 to the blood pump 10.").

79. Further, Ozaki (U.S. Patent No. 6,589,030; Ex.1024) also uses "magnetic-coupling" to refer to a transfer from one rotating permanent magnet on a motor to another permanent magnet on a rotor:

> Motor unit 140 houses a motor 141 and a rotor 142. Rotor 142 has a surface facing pump unit 130 and having a permanent magnet 143 buried therein opposite to permanent magnet 132 of impeller 131 with a partition 104 posed therebetween. …

> [A] significant attractive force created by permanent magnets 132 and 143 configuring **magnetic-coupling**.

Ex.1024, 1:29-33, 1:60-61.

80. Yet another reference, Araki (European Patent No. 0 834 326 B1; Ex.1025), uses "magnetic-coupling" to refer to a transfer from one rotating permanent magnet on a motor to another permanent magnet on a rotor:

> FIG. 1 schematically shows a construction of the present invention. The casing 3 comprises an inlet 1 at its upper end and an outlet 2 at the bottom thereof. In a plurality of the vanes of the impeller, driven magnets 15 in the magnet casing 14 at the lower portion is **magnetically coupled** with the driving magnet 16 located out of the casing 3. **Driving magnet 16 is rotated by a motor placed out of the pump. As a result, the impeller containing the driven magnet 15 is rotated** so as to supply energy to the blood.

Ex.1025 at [0039].

81. The fact the 077 Patent's specification and these prior art references—Schob 2002, Qian, Masuzawa, Aboul-Hosn, Ozaki, and Araki—all consistently use "magnetic coupling" to refer to a transfer of torque from one rotating permanent magnet to another rotating permanent magnet via a magnetic field supports my opinion as to the plain and ordinary meaning of *magneto coupling*.

82. In addition to the prior art, the 077 Patent itself refers to an international patent application (WO 01/70300 A1, later filed at the USPTO as U.S. Pat. App. No.

10/239,602 and published as U.S. Pat. Pub. No. 2003/0124007A1 to Schima et al. ("Schima," Ex.1005)) which describes a rotor that may either be driven by "a rotating magnetic field" created by a "stator" having "coils," or alternatively, "the drive can also be an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25" (i.e., magnetic coupling). Ex.1005, [0012], [0013]. Schima discloses that the latter embodiment using magnetic coupling "has the advantage that no electrical energy is used to journal the rotor." Ex.1005, [0013].

83. As discussed above, the 077 Patent discloses only this latter method of driving rotation of the rotor, and in fact, the specification explicitly states that an "external electromagnetically driven pump," i.e., drive by magnetic levitation, "is not directly suitable" for the described invention. Ex.1001, 3:17-36 ("The rotor itself can follow design principles such as described for example in WO 01/70300 A1. The rotary pump shown and described there for conveying blood and other highly sensitive fluids is formed as an external electromagnetically driven pump which is **not directly suitable** for incorporation into a catheter."). Thus, the 077 Patent's specification is consistent with Schima in addition to the prior art references described above in that they all consistently distinguish between drive using magnetic coupling and drive using magnetic levitation technology.

b. The Patent Owner conflates magnetic coupling with other types of drive.

84. Patent Owner wrongly conflates magnetic coupling with other types of drive, such as drive by magnetic levitation. I have reviewed the Patent Owner's complaint served in the parallel litigation, and I understand that the Patent Owner accuses the HeartMate 3 Left Ventricular Assist System (LVAS) of infringing Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent. In doing so, I understand that the Patent Owner's apparent construction of "magneto coupling" is not limited to the term's plain and ordinary meaning (a transfer of torque from one rotating permanent magnet to another rotating permanent magnet), but broadly includes a transfer of torque from one **stationary** magnetic component (i.e., a stator) to another rotating magnetic component using an **electro**magnetic field (i.e., drive by magnetic levitation). *See* Ex.1019, Exhibit 13 of Complaint, 7-12 (identifying "Motor, Stator, and/or MagLev Flow Technology" as "configured to orient the magnetically driven rotor in its housing via the magneto coupling between the second magnetic device and the first magnetic device"). That is, Patent Owner interprets "magnetic coupling" to include the application of torque to a rotor generated by an electric motor via an electromagnetic field (i.e., magnetic levitation technology).

85. I disagree with the Patent Owner's broad construction of this term. Both the patent specification and the extrinsic evidence are consistent with my understanding of "magneto coupling" to refer to the narrower definition of a transfer of torque from one rotating permanent magnet to another rotating permanent magnet.

86. To the extent the Patent Owner argues that a "magneto coupling" exists between a stationary magnetic component, such as a motor stator, and a rotating permanent magnet because the stationary magnetic component generates a rotating magnetic field, I disagree. That definition does not comport with the plain and ordinary meaning of "magneto coupling" in view of the 077 Patent specification and the extrinsic evidence, as discussed above.

87. In any event, even if "magneto coupling" is broadly interpreted under the Patent Owner's understanding, my narrower understanding of the plain and ordinary meaning term to refer to "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field" would be also included in such a broad interpretation.

2. "the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and" (Claim 1)

88. The plain and ordinary meaning of this claim limitation is that it means a "hydrodynamic bearing." In my opinion, a POSITA as of February 27, 2007 would

have understood the plain and ordinary meaning of "by the gap sized for passage of the blood" to mean that the blood flowing in response to rotation of the magnetically driven rotor ***causes*** the magnetically driven rotor to remain entirely spaced apart from the surrounding rotor housing. A POSITA would therefore understand this limitation to refer to, for example, the "the gap sized for passage of the blood" being used as a hydrodynamic bearing to assist in suspending the magnetically driven rotor such that it remains entirely spaced apart from the surrounding rotor housing while the magnetically driven rotor is in rotation.

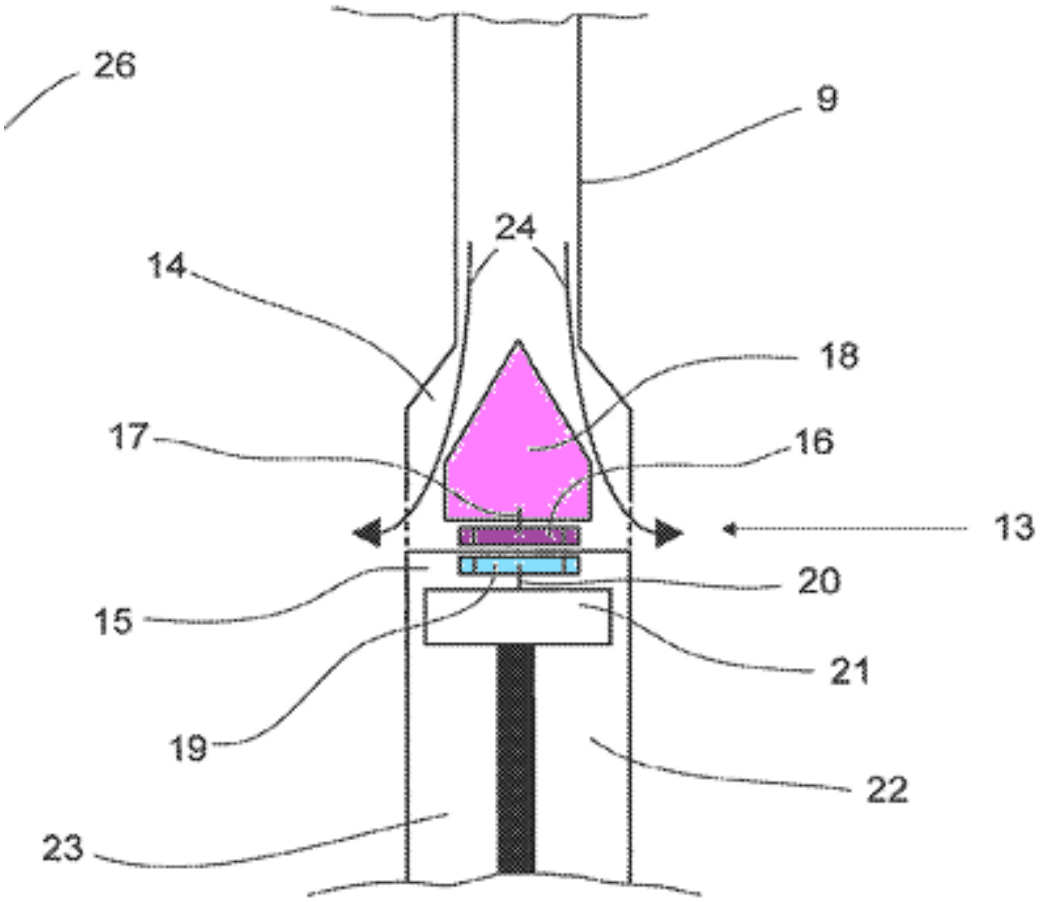
a. The specification and prior art consistently use this claim language to refer to a hydrodynamic bearing.

89. As described above, LVADs use three types of bearings—mechanical, hydrodynamic, or magnetic, either alone or in combination. Mechanical bearings rely on physical contact between components to stabilize a rotor in the housing during rotation. Magnetic bearings, such as described in Bourque-2001 for the HeartMate III device (see Section IX.B), use electromagnets to levitate and stabilize a rotor without physical contact.

90. A "hydrodynamic bearing" (also known as a fluid bearing), which was a well-known and commonly used term in the art when the 077 Patent was filed, uses motion to create a pressure that forces a rotating component, such as a rotor,

apart from a surface by a fluid flowing between the rotating component and the surface. *See, e.g.*, Ex.1008, [0092]. The history of hydrodynamic bearings dates to the 19th century. As Qian describes it, there is a "'taking off' of the rotor [that] is generated by a hydraulic force (a reacting force of the flow), which acts on the impeller because the impeller propels the flow." Ex.1016 at 37, abstract ("the axial levitation is produced by hydraulic force"). The stationary surface (here, the pump housing) and rotating surface (here, the rotor) are separated by a thin film of fluid (here, blood) when the rotor is in rotation. The film pressure that separates the surfaces is created by the relative motion (rotation) of the surfaces as the lubricant is pulled into a converging geometry between the surfaces.

91. While Claim 1 does not recite the use of a "hydrodynamic bearing," that meaning is the only logical interpretation of the limitation as recited in Claim 1 when read in light of the 077 Patent's specification. This limitation recites that "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the blood flowing** …" For example, Figure 2 (annotated and enlarged) of the 077 Patent shows that the "bar magnet 19" (**light blue**) is spaced apart from the "bar magnet 16" (**purple**) and the "rotor 18" (**pink**) is spaced apart from the walls of the tube 9 while the blood is flowing as indicated by arrows 24:



Ex.1001, Fig. 2 (annotated). In order for the "magneto coupling" to orient the "magnetically driven rotor" to remain entirely spaced apart from the surrounding rotor housing by the gap sized for passage of the blood, and without the recitation of a magnetic bearing or other non-contact bearing, the limitation must refer to the pressure created between the rotor and the housing by the gap sized for passage of the blood to cause suspension of the magnetically driven rotor in the surrounding

rotor housing such that it is not in contact with the housing. By definition, that suspension is a hydrodynamic bearing.

92. This hydrodynamic suspension of the rotor is disclosed in the Schima application, which the 077 Patent incorporates by reference. Ex.1001, 2:29-34 ("The rotor itself can follow design principles such as described for example in WO 01/70300 A1."). For example, Schima discloses "a rotor 1 that is formed of two superposed conical sleeves 31 and 32 that are connected together by centrifugal vanes or flow surfaces 33. Rotor openings 18 and the outer vanes 4 serve to produce the flow component 5 against the upper part 15 of the housing as well as against the conical middle part 16 of the lower housing part 19. **In this manner the rotor is hydrodynamically stabilized in the housing**." Ex.1005, [0019]. Claim 1 of the Schima application recites "a rotor journaled hydraulically and if necessary magnetically in a housing," which includes "flow components (5) directed against the housing serving mainly for contact-free journaling and stabilizing of the rotor in the housing." Ex.1005, Claim 1. This understanding from the 077 Patent's claims and specification is consistent with the use of the term "hydrodynamic bearing" in the art as of February 27, 2007. In addition to Qian described above, Wampler-169 similarly describes that, "hydrodynamic bearings can be located on the surface of [an] impeller to constrain axial motion and to provide radial support in the case of

eccentric motion or shock on the device." Ex.1008, [0089]. Specifically, Wampler-169 discloses that the "hydrodynamic bearings" can be "formed by a raised pad **spaced from a contact surface by the blood gap**. Although at rest there may be contact between the impeller and the casing, **once rotation begins** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap **which forces the raised pad and the contact surface apart**." Ex.1008, [0092].

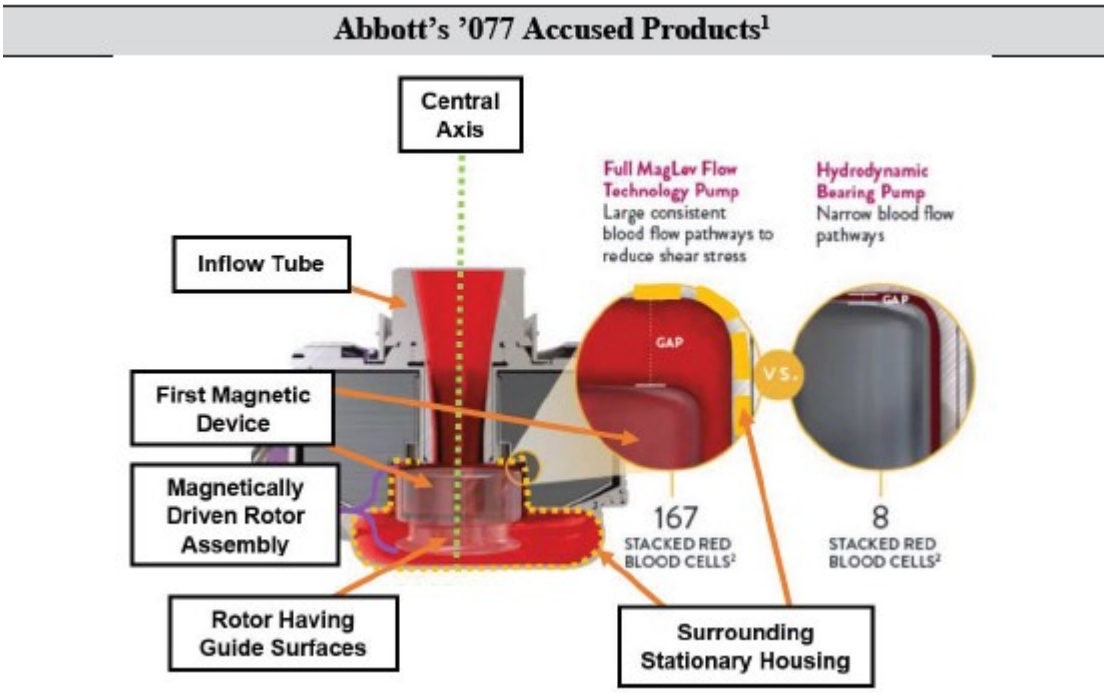
93. I note that while the 077 Patent does not disclose the use of "pads" as discussed for example in Wampler-169, the "outer vanes 4" on the rotor described in Schima (incorporated by reference into the 077 Patent) serve the same purpose: "to produce the flow component 5 against the upper part 15 of the housing" such that "the rotor is hydrodynamically stabilized in the housing." Ex.1005, [0019].

94. Thus, Schima discloses the rotor (which is incorporated by reference in the 077 Patent specification) is suspended hydrodynamically, and if necessary, magnetically. Because Claim 1 of the 077 Patent recites only that the magneto coupling orients the magnetically driven rotor" to remain entirely spaced apart from the surrounding rotor housing "by a gap sized for passage of the blood," and not, for

example, **by a magnetic bearing**, a POSITA would understand the limitation to mean that the "blood flowing" causes the separation.

b. The Patent Owner renders this claim language meaningless.

95. I have reviewed the Patent Owner's complaint served in the parallel litigation, and I understand that the Patent Owner accuses the HeartMate 3 Left Ventricular Assist System (LVAS) of infringing Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent. I understand that in doing so, the Patent Owner's apparent construction of this claim term is not limited to the term's plain and ordinary meaning (i.e., hydrodynamic bearing) but broadly includes that it may be met *exclusively* by magnetic suspension. However, the Patent Owner's apparent construction of this claim limitation reads out or renders the phrase "by a gap sized for passage of the blood" meaningless, which I understand is improper. Patent Owner's interpretation appears to capture rotor suspension using a magnetic bearing ("MagLev Flow Technology"; **green**) instead of a hydrodynamic bearing (**red**), as shown in as shown by PO's complaint distinguishing the two bearing types:



Ex.1019, at 8.

96. Ignoring this claim language, the Patent Owner asserts that the HeartMate 3 device meets this limitation even though the accused device obviates the need for a hydrodynamic bearing. *See* Ex.1019, Exhibit 13 of Complaint, 8 (comparing benefit of "Full MagLev Flow Technology Pump" "vs." "**Hydrodynamic Bearing** Pump"). The magnetically driven rotor of the accused device, however, is instead supported only by magnetic levitation.

97. I disagree with the Patent Owner's broad construction of this term that includes magnetic suspension of the magnetically driven rotor (i.e., a magnetic bearing). As I discuss above, a POSITA would understand the plain and ordinary

meaning of the limitation to require that the "blood flowing" causes the magnetically driven rotor to remain spaced apart from the surrounding rotor housing.

98. In any event, even if the "by a gap sized for passage of the blood" limitation is broadly interpreted under the Patent Owner's understanding (that the limitation is met by a magnetic bearing), my interpretation of the plain and ordinary meaning of this limitation would nonetheless be included in such a broad interpretation. Said another way, this term should mean a "hydrodynamic bearing." Or if Patent Owner's apparent construction is correct, then the term should include either a "hydrodynamic bearing" or a "magnetic bearing."

VIII. IDENTIFICATION OF HOW THE CLAIMS ARE UNPATENTABLE

99. A POSITA would find the challenged claims unpatentable under any interpretation consistent with their plain and ordinary meaning. The following discussion in this Declaration provides a detailed analysis of how the asserted prior art teaches each limitation of the Challenged Claims.

100. As part of my analysis, I have considered, and discuss in detail, the scope and content of the prior art and any differences between the alleged invention and the prior art.

101. It is my opinion that the alleged invention recited in the Challenged Claims is anticipated and/or would have been obvious in view of the teachings of the asserted prior art and the knowledge of a POSITA.

IX. THE PRINCIPAL PRIOR ART

A. Summary of Wampler-169

102. U.S. Pat. Pub. No. US 2002/0102169A1 to Richard K. Wampler, titled "Sealless Rotary Blood Pump" (Ex.1008, "Wampler-169") was published August 1, 2002 and issued February 10, 2004 as U.S. Pat. 6,688,861. I understand that Wampler-169 is therefore prior art to the 077 Patent at least under 35 U.S.C. § 102(b).

103. Wampler-169 seeks to address the problems faced by patients with "left ventricular heart failure" who "could benefit from cardiac transplantation," but are unable to receive a donor. Wampler-169 states that "if a left ventricular assist device ("LVAD") were available for chronic use, many of these patients could be returned to prolonged and productive lives." Ex.1008, [0003]. Wampler-169 explains that "[p]rior art LVADs…provide a cyclic or pulsating delivery of blood to emulate the natural pulsatile blood through the heart." Ex.1008, [0004]. However, these cyclic delivery systems presented "anatomic and engineering problems" due to their physically large size and complexity, making implantation difficult and expensive.

Ex.1008, [0004]. Further, while rotary pumps, as opposed to cyclic pumps, "provide substantially continuous liquid flow," "the prior art has not developed a durable rotary blood pump, owing to unique problems with the rotary pump's driveshaft seal," which have a "short life" and "contribute to a premature failure of the pump." Ex.1008, [0005].

104. Accordingly, Wampler-169 discloses "a small centrifugal pump" that "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0065], [0076]. This "implantable rotary sealless blood pump" that "advantageously" uses "magnets…in the pump drive system" such that "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing," which eliminates the need for a driveshaft seal and thereby allows for a mechanically frictionless system. Ex.1008, [0006], [0018].

105. Figure 5 of Wampler-169 illustrates the positioning of the rotary sealless blood pump having an "inlet tube 13" (see Fig. 13) that serves as the "inflow cannula" implanted within the left ventricle of a heart:

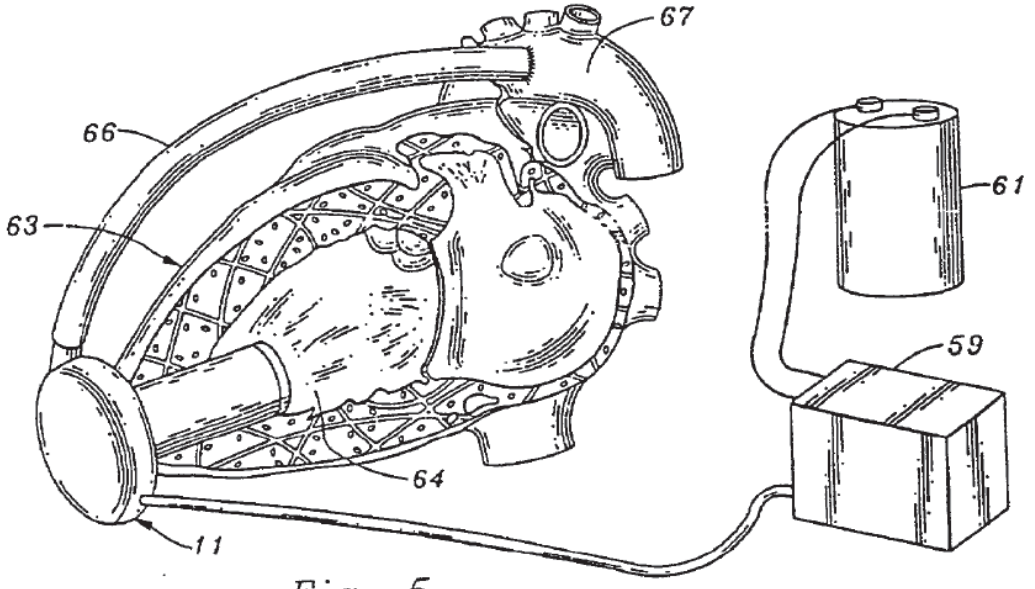
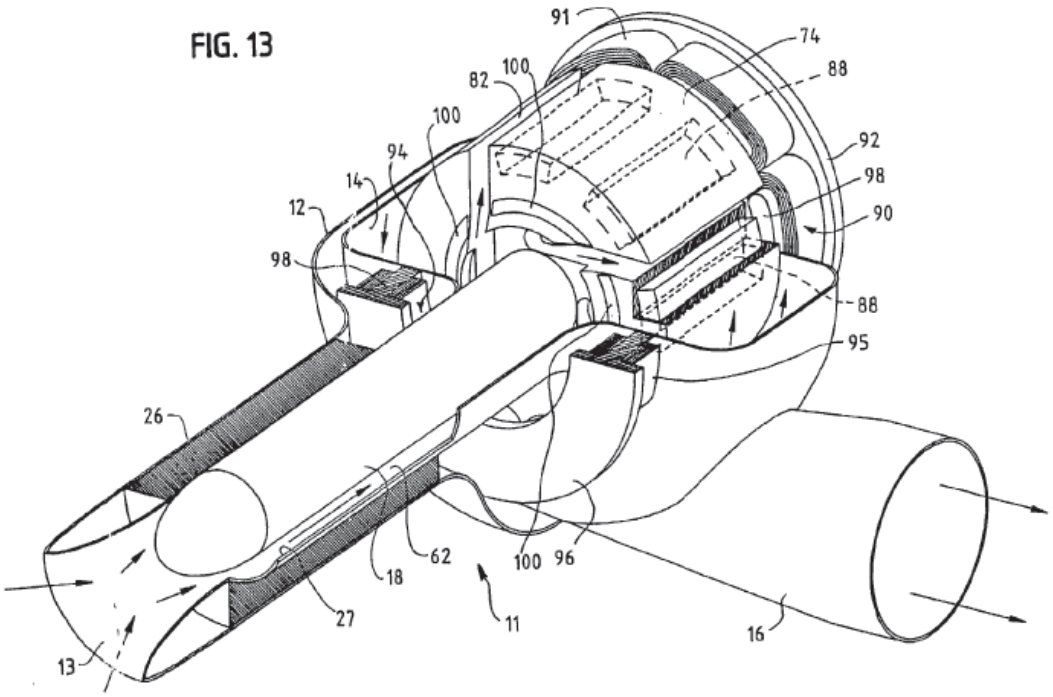


Fig. 5

Ex.1008, Fig. 5, [0050].

106. In embodiments described with respect to FIGs. 11-16, the "blood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGs. 1-8, and includes housing 12, having an elongated inlet tube 13, and a scroll-shaped impeller casing or volute 14. A discharge tube 16 extends through the housing to communicate with the interior periphery of casing 14." Ex.1008, [0080]. "Pump rotor 17 is located within the housing 12, within casing 14, and includes an elongated right-circular cylindrical support shaft or spindle 18, attached to impeller 74." Ex.1008, [0081]. Figure 13 of Wampler-169 illustrates a perspective, partially broken for clarity view of the pump 11 having the impeller 74:



Ex.1008, Fig. 13.

107. Wampler-169 teaches that the rotor 17 is driven via an "electromagnetic field." Ex.1008, [0072]. In the embodiment described with respect to FIGs. 1-8, "a brushless rotor motor 53 includes arcuate magnetic segments 54, imbedded within the upper face portion 36 of blade sectors 49" of the impeller 19. Ex.1008, [0070]. The "segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56," which includes "windings 57 and a circular pole piece or back iron 58, mounted on the outer surface of impeller casing 14." Ex.1008, [0070]. "The windings 57 are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole

piece 58, and is effective to drive magnets 54 and the rotor 17, in rotary fashion." Ex.1008, [0072]. Wampler-169 discloses that the "[m]otor 53, with windings 57 and pole piece 58, together with magnets 54, function not only to transmit torque but also provide a restoring radial magnetic force that acts as a radial bearing." Ex.1008, [0073].

108. Wampler-169 describes the resulting blood flow path, where "[r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62." Ex.1008, [0074]. Finally, "[d]ischarge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system. Ex.1008, [0074].

109. In the embodiment described with respect to FIGs. 11-16, the mechanism by which the electromagnetic field drives the magnetic pieces 88 to thereby rotate the rotor 17 is the same, except that the motor consists of a "first motor stator 90, comprising conductive coils or motor windings 91…located at the rear of the impeller 74," and a "second motor stator 94, comprising windings 95, is positioned on the forward side of the impeller 74." Ex.1008, [0083]-[0084].

110. In this embodiment, Wampler-169 discloses that "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device."

Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093]. "The hydrodynamic bearings are formed by a raised pad spaced from a contact surface by the blood gap. Although at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap which forces the raised pad and the contact surface apart." Ex.1008, [0092].

111. Wampler-169 also discloses percutaneous wires that connect the pump to a "controller" that may be "worn externally by the user." Ex.1008, [0070]. "Controller 59 may include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump" or "may also have interactive and automatic capabilities." Ex.1008, [0071]. The controller may be interconnected to sensors to "tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0070], [0071].

B. Summary of Bourque-2001

112. Bourque et al., *HeartMate III: Pump Design for a Centrifugal LVAD with a Magnetically Levitated Rotor* (Ex.1007, "Bourque-2001") was published in the American Society for Artificial Internal Organs (ASAIO) Journal in 2001.

113. I understand that a prior art reference is proven to be a "printed publication" upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

114. Bourque-2001 would have been disseminated or otherwise made available to the extent that a POSITA, exercising reasonable diligence, could have located it as of the time of its publication in ASAIO Journal in 2001. Ex.1030 (Hall-Ellis Dec.) at ¶¶45-52. In addition, Bourque-2001 was cited in at least 29 other publications prior to the February 27, 2007 priority date of the 077 Patent.[14] I understand that Bourque-2001 is therefore a printed publication prior art to the 077 Patent at least under 35 U.S.C. § 102(b).

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[14] *See* Google Scholar search results for articles citing Bourque-2001 prior to 2007 (accessed via https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=9100739476171713774&scipsc=&as_ylo=&as_yhi=2006) (last accessed Nov. 3, 2024).

115. The "HeartMate III" device described in Bourque-2001 appears to be designed in a very similar manner as the HM3 device accused of infringement in the parallel litigation. *See* Ex.1019, Exhibit 13 of Complaint.

116. Bourque-2001 describes the design and testing of a "long-term, compact left ventricular assist device (LVAD)," known as the HeartMate III. Ex.1007 at 401. Bourque-2001 describes that at the time of the publication, "[e]ach year in the United States, 400,000 people are diagnosed with congestive heart failure (CHF), some of whom are eligible for heart transplant (1% or so), but many of whom are not." Ex.1007 at 401. Accordingly, "[t]he advent of the left ventricular-assist device (LVAD) has provided significant benefit to certain CHF patients since becoming clinically available. These devices seek to ameliorate increases in mortality due to the divergence of the increasing population of those awaiting cardiac transplant and the somewhat dwindling availability of organs." Ex.1007 at 401.

117. Bourque-2001 states the LVADs that were clinically available at the time were positive-displacement-type pumps that "contain[ed] mechanical parts that wear, such as ball bearings, flexible diaphragms or sacs, and valves." Ex.1007 at 401. The "second generation of LVADs" (*e.g.*, HeartMate II) were "continuous flow-type pumps," which exploit inherently fewer mechanical parts and additional

benefits such as a smaller size and lower cost. Ex.1007 at 401. Accordingly, HeartMate III as described in Bourque-2001 intended to feature these qualities while also eliminating the problems of all mechanical bearings.

118. Instead, the HeartMate III features "a centrifugal pump with a magnetically levitated rotor" and "[t]he rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. The HeartMate III described in Bourque-2001 was designed "to achieve a design point of 7 L/min against 135 mm Hg at high hydrodynamic efficiency (30%) and to be capable of up to 10 L/min under such a load." Ex.1007 at 401.

119. The HeartMate III in its implanted configuration is illustrated in Figure 3 of Bourque-2001:

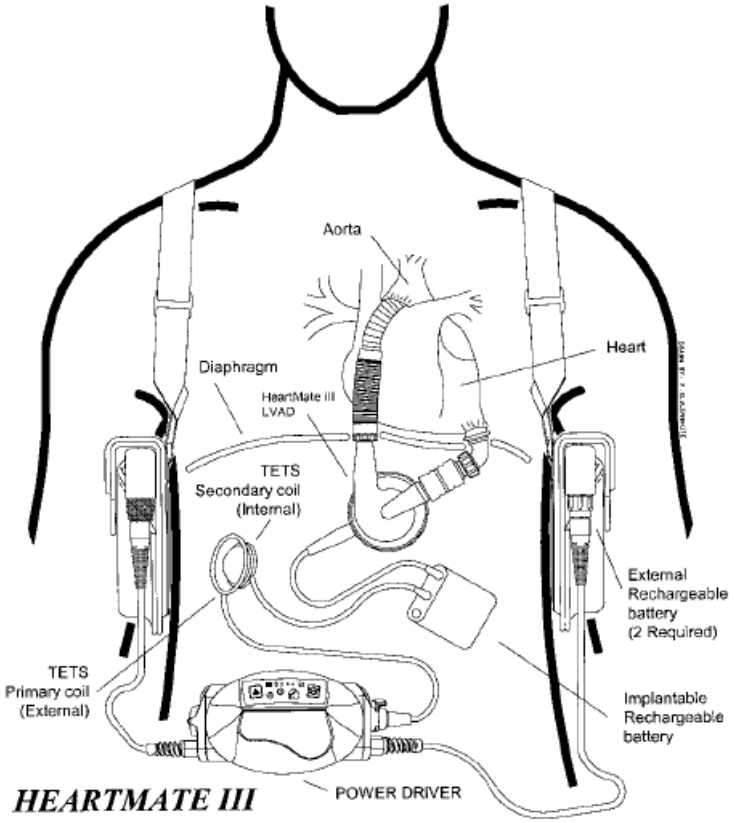


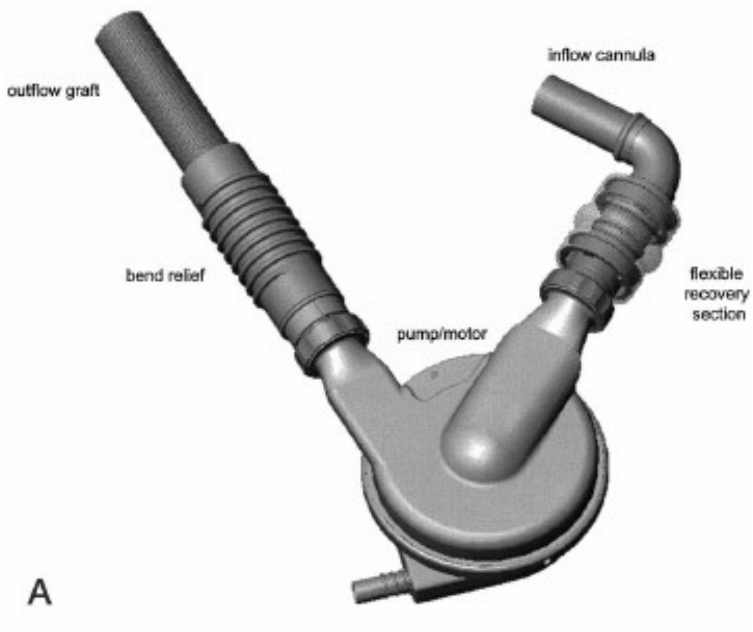
Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3.

120. The HeartMate III pump described in Bourque-2001 includes an "upper housing that includes the inflow and outflow channels and the upper half of the volute; a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed; a rotor that includes an impeller and passively magnetic elements;" "an inflow subassembly that includes a left ventricular (LV) cannula"; an "outflow subassembly"; "an electronic cable to be exteriorized percutaneously"; and additional subcomponents and hardware. Ex.1007 at 401.

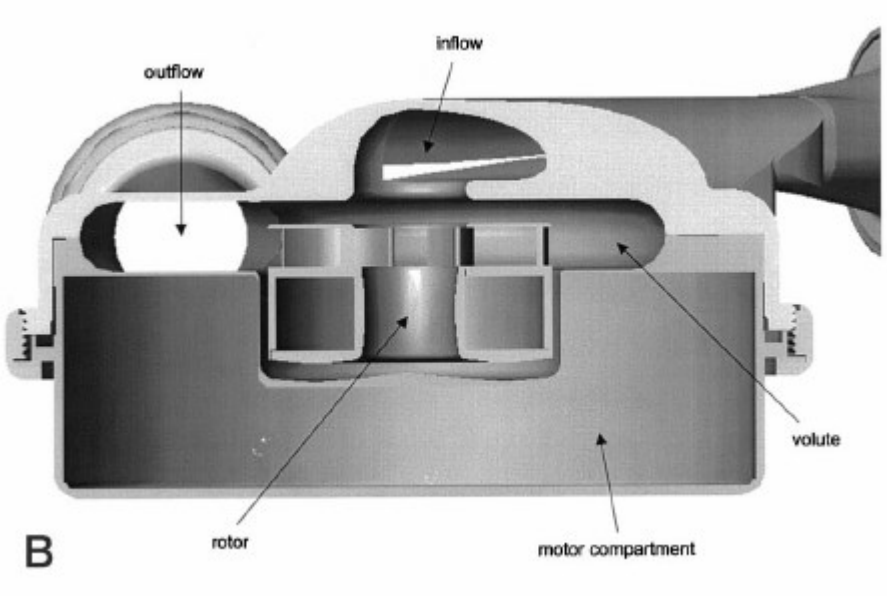
121. In this explanation, Bourque-2001 describes the "impeller" as being part of the "rotor." A POSITA would understand that the impeller is the part in contact with the blood that provides the pumping action, and the impeller is enclosed within the rotor. The rotor also includes passively magnetic elements. Ex.1007 at 401. The rotor is a single integral part which includes the impeller. The rotor described in Bourque-2001 appears to be designed in the same manner as the rotor of the HM3 device accused of infringement in the parallel litigation. *See* Ex.1019, Complaint, Ex. 13.

122. Figure 1A of Bourque-2001 illustrates an overall view of the HeartMate III pump:



Ex.1007, Fig. 1A.

123. Figure 1B of Bourque-2001 illustrates a cross-sectional view of the HeartMate III pump:

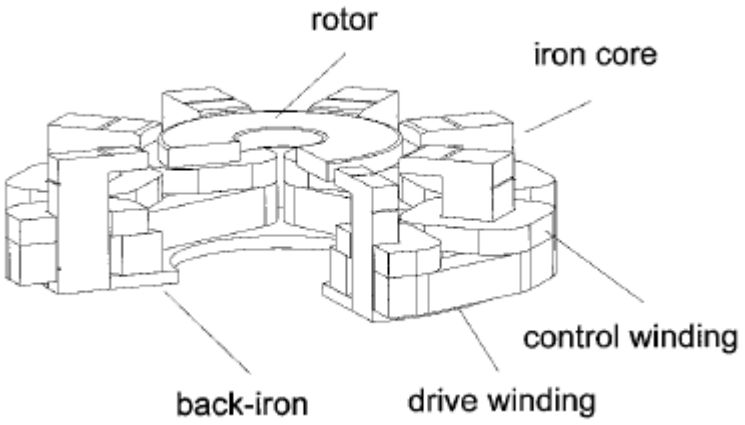


Ex.1007, Fig. 1B.

124. "The flow path is of circular cross-section through the inflow and outflow sections." Ex.1007 at 402. Blood enters the impeller through an opening in the "shroud (i.e., the cover across the top of the blades on the rotor)," and "exits the backswept blades of the impeller into a volute of uniformly increasing width." Ex.1007 at 402. Backflow clearances above and below the rotor allow space for the magnetic levitation of the rotor while balancing "reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402. These backflow clearances were also "constrained by the stiffness of the magnetic suspension

(passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position" and "permit up to 7× gravitational loads in any direction without contact between the rotor and housing." Ex.1007 at 402.

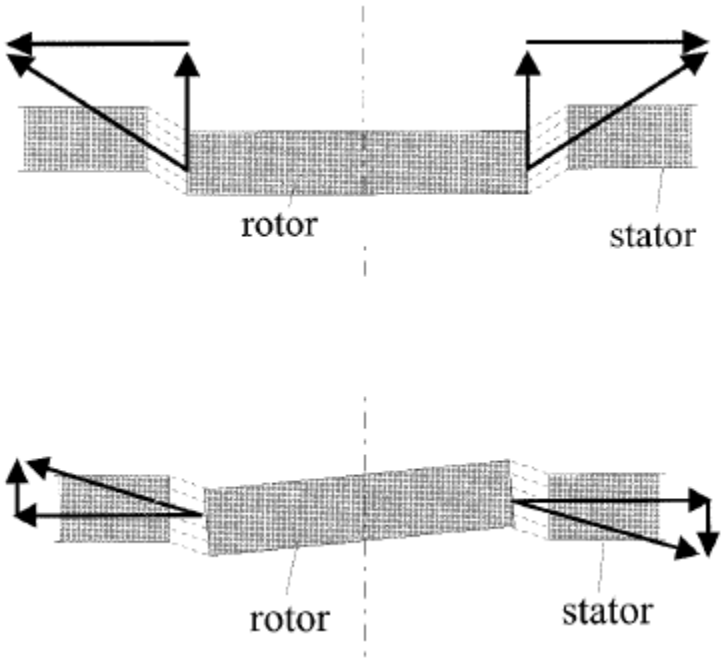
125. Figure 4 of Bourque-2001 illustrates the HeartMate III motor which includes "drive and levitation (control) in a single magnetic structure":



Ex.1007, Fig. 4.

126. Bourque-2001 discloses that "[t]he rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom…and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

127. Figure 5 illustrates the passive magnetic levitation of the rotor which causes both a restoration force under axial-translational (above) and transverse-rotational (below) degrees of freedom:



Ex.1007 at 404, Fig. 5.

128. The "stators" illustrated in Figure 5 are stationary parts of the system that create a magnetic field when a current is applied to the windings around the cores (refer to Ex.1007, Fig. 4) causing the rotation of the rotor. Bourque-2001 discloses that "[t]he very simple main flow path is a consequence of the motor's "J" core configuration (i.e., the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the

motor and levitation elements, and above which the hydrodynamic elements are permitted free reign"). Ex.1007 at 404.

129. For the testing of the HeartMate III device described in Bourque-2001, "[t]he electronics for power and control of the LVAD and for data acquisition resided on a shelf." Ex.1007 at 403. In addition, the *in vivo* testing described in Bourque-2001 was performed on bovines. However, "the only difference between the pump used for *in vivo* studies and the eventual human configuration is the presence of the elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans." Ex.1007 at 405.

C. Summary of Akamatsu-1999

130. The scientific journal by Nojiri, C., Maekawa, J., Kido, T., Mori, T., Asada, T., Suzuki, M., & Akatsu, T., Kijima, T., Horiuchi, K., Sugiyama, T., Sugiura, N., Ozaki, T., and Akamatsu, T., titled *Development of Terumo implantable left ventricular assist system (T-ILVAS) with a magnetically suspended centrifugal pump*, Japanese Society for Artificial Internal Organs, 2:3-7 (1999) is referred to herein as "Akamatsu-1999" (Ex.1006).[15] I understand that a prior art reference is

[15] Although the first-author of Ex.1006 is Nojiri, numerous other articles discussing the development of this same Terumo device list Akamatsu as the first author. For ease of reference, they are referred to collectively as Akamatsu references.

proven to be a "printed publication" upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

131. Akamatsu-1999 would have been disseminated or otherwise made available to the extent that a POSITA, exercising reasonable diligence, could have located it as of the time of its publication in the Japanese Society for Artificial Internal Organs Journal in 1999. Ex.1030 (Hall-Ellis Dec.) at ¶¶53-60. In addition, Akamatsu-1999 was cited in at least 5 other publications prior to the February 27, 2007 priority date of the 077 Patent.[16] I understand that Akamatsu-1999 is therefore prior art to the 077 Patent at least under 35 U.S.C. § 102(b).

132. Akamatsu-1999 describes that as of the publication date, "[r]otary blood pumps, such as the axial flow pump and the centrifugal pump, are being developed worldwide as implantable ventricular assist systems (VAS). The advantages of the rotary blood pump are its compactness, simplicity, and low cost."

[16] *See* Google Scholar search results for articles citing Akamatsu-1999 prior to 2007 (accessed via https://scholar.google.com/scholar?hl=en&as_sdt=5%2C33&sciodt=0%2C33&cites=4553201015857277871&scipsc=&as_ylo=&as_yhi=2006) (last accessed Nov. 3, 2024).

Ex.1006 at 3. Akamatsu-1999 accordingly describes the design and development of "an implantable left ventricular assist system (T-ILVAS) featuring a centrifugal blood pump, with a magnetically suspended impeller (MSCP)." Ex.1006 at Abstract. "Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is expected to be one of the most durable blood pumps." Ex.1006 at 3.

133. The design of the Akamatsu-1999 centrifugal pump was "composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor." Ex.1006 at 4. Figure 2 of Akamatsu-1999 illustrates a schematic cross section of the centrifugal pump:

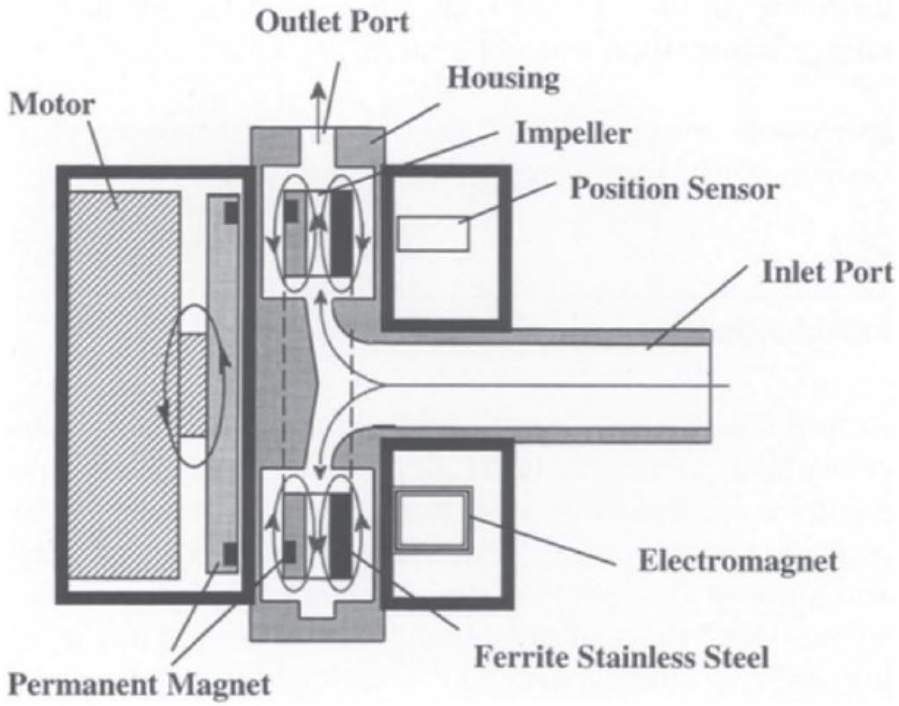


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2.

134. Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets. The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4. During the testing described in the study, "the inflow conduit was inserted into the left ventricle through a cuff sutured to the left ventricular apex." Ex.1006 at 4.

135. Akamatsu-1999 discloses that during the described testing, "[t]he pump was operated at a fixed rotational speed." Ex.1006 at 4, 5; *see also* Ex.1006 at 7 ("The implantable controller has different driving modes, including a fixed rotational speed mode, a fixed motor current mode, a controlled motor current mode, and a pulsatile mode."). In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5.

136. Figure 1 of Akamatsu-1999 illustrates the T-ILVAS in its implanted configuration in the ventricle of the heart:

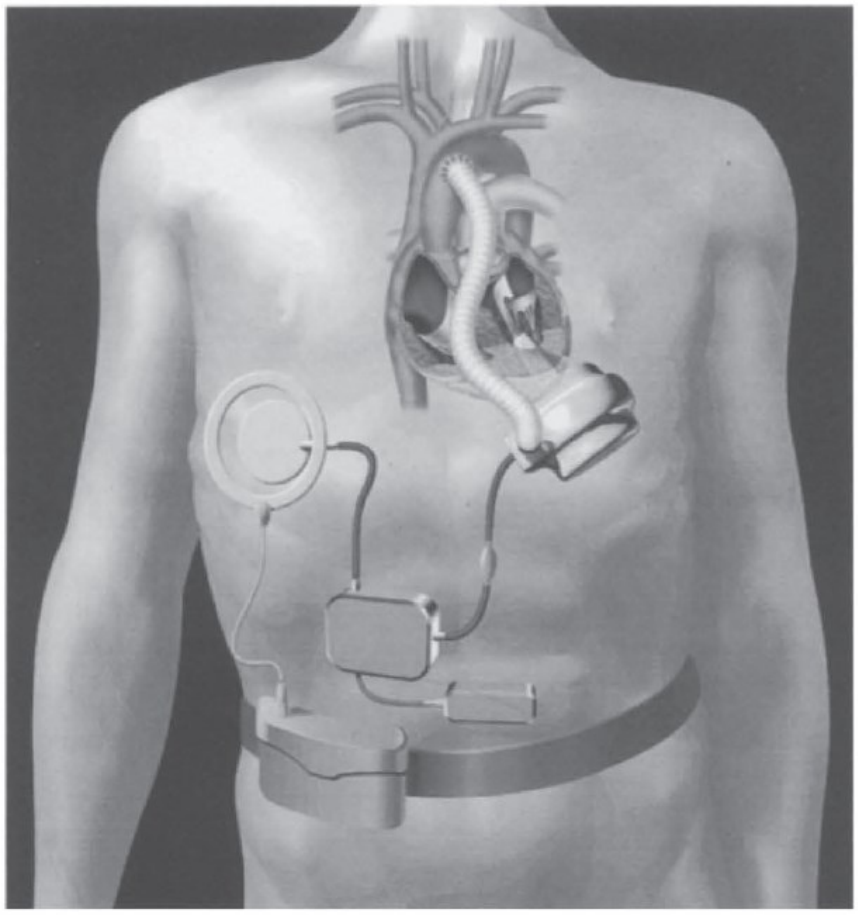


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, at Fig. 1

D. Summary of Schima

137. U.S. Pat. Pub. No. US 2003/0124007A1 to Heinrich Schima, et al., titled "Rotary Pump Comprising a Hydraulically Mounted Motor" (Ex.1005, "Schima") was published July 3, 2003. I understand that Schima is therefore prior art to the 077 Patent at least under 35 U.S.C. § 102(b). Schima claims priority to international PCT No. PCT/AT01/00086 (WIPO No. WO 01/70300 A1), originally

filed in Austria in German language. The 077 Patent specification references that same Schima priority WIPO application stating that "[t]he rotor itself can follow design principles such as described for example in WO 01/70300 A1."

138. I note that the German language application (WO 01/70300 A1) was included in the Information Disclosure Statement to the USPTO and is therefore listed on the face of the 077 Patent as a foreign reference cited. However, based on my review of the 077 Patent prosecution history, and the prosecution histories of related patents in the same family, the English language version of Schima that I discuss herein was never disclosed by the applicant to the USPTO, nor was it used as the basis of any rejection of the patent application leading to the 077 Patent during prosecution.

139. Schima seeks to address problems with existing heart assist pumps at the time. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow and dead-water areas" could create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

140. According to Schima, "solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. Schima describes a number of existing heart assist pump devices that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. However, Schima states that each of those existing solutions had drawbacks, including with respect to complexity, cost, and effectiveness. Ex.1005, [0004], [0005], [0006], [0007], [0008].

141. Therefore, Schima sought to overcome those disadvantages by its disclosure of a rotary pump for moving blood and other shear-sensitive liquids, that has a rotor 1 that is "journaled hydraulically and, if necessary, magnetically in a housing" such that it may rotate "contact-free" from the housing." Ex.1005, [0001], [0010], Abstract, Claim 1.

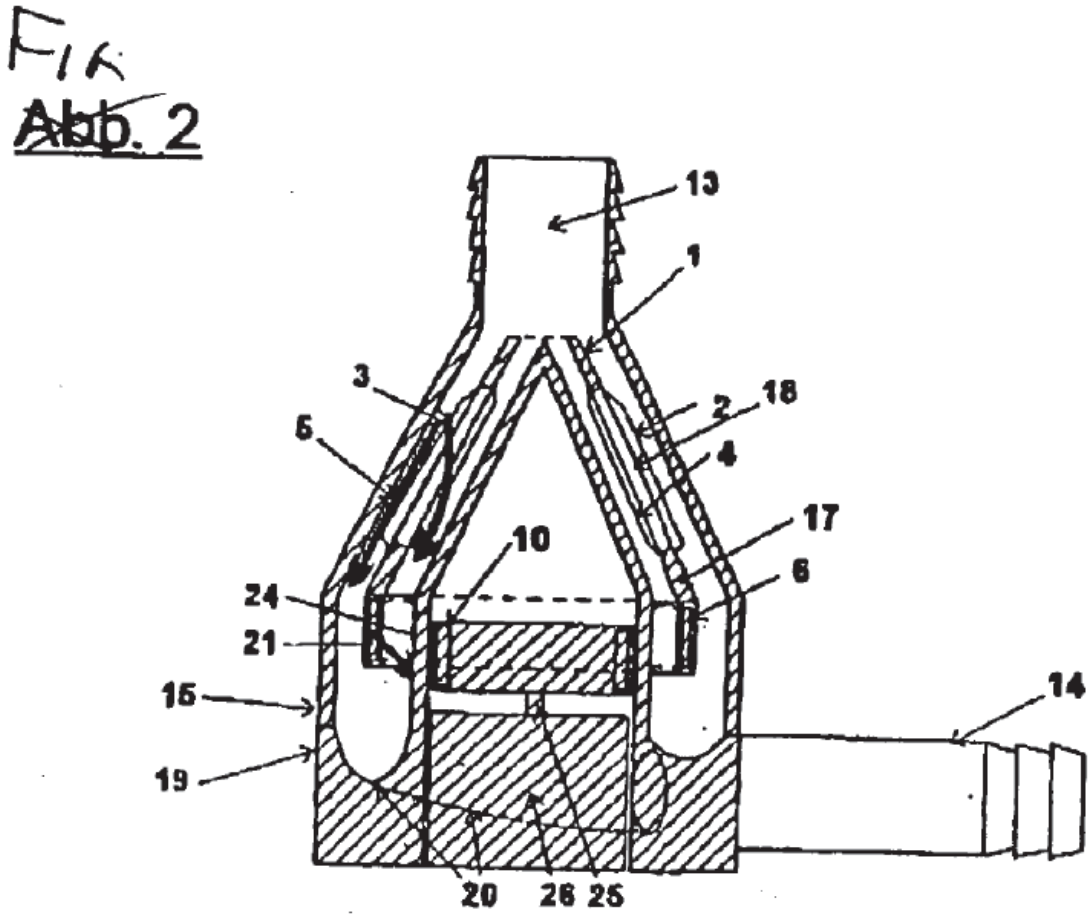
142. The "rotor 1" of the pump described in Schima "has as flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5 directed against the housing." Ex.1005, [0012]. "This hollow conical rotor 1 rotates in a pump housing 30 comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, centering of the hollow conical rotor in the middle part 16 of the housing lower part 19 being effected by the flow components 5 directed against the housing, this flow being preferably axially against the conical upper surface of the middle part 16." Ex.1005, [0012]. In addition, the

centering can "be wholly or additionally effected by flow components (5) directed against the housing or centrifugally (3) against the hollow conical upper part 15." Ex.1005, [0012].

143. "The rotor 1 has at an inlet 13 an inlet opening 36 that distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16." Ex.1005, [0012]. "A spiral-shaped outlet passage 20 in the lower housing part 19 leads to an outlet 14" of the pump. Ex.1005, [0012].

144. In order to drive rotation, "[t]he rotor holds rotor magnets 6 that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. In an embodiment of the rotor 1, that "drive" can be "an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25. This embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the magnetic force 21." Ex.1005, [0013].

145. Figure 2 of Schima illustrates a cross-sectional view of the embodiments of the pump described above having the rotor 1 driven by the "rotor magnets 6" transferring of rotation energy from the "magnets 10" within the "rotating disk 24" driven by the "electric motor 26" via the "magnetic force 21":



Ex.1005, Fig. 2.

X. CLAIMS 1-5, 7, 10, 16-24, 26, AND 28 OF THE 077 PATENT ARE ANTICIPATED AND/OR RENDERED OBVIOUS BY THE PRIOR ART

146. As an initial matter, I will summarize the grounds of my analysis. Because there are two potential interpretations for each of two different claim terms—the "magneto coupling" term and the "by a gap sized for passage of the blood" term—there are four permutations of the potential claim interpretations. The claims are anticipated and/or rendered obvious under all four permutations:

i. **Ground 1:** Wampler-169 alone applies the Patent Owner's apparent broad interpretation of "magneto coupling" and my narrower interpretation of the "by a gap sized for passage of the blood …" term.

ii. **Ground 2:** Bourque-2001 in view of Wampler-169 applies the Patent Owner's apparent broad interpretation of "magneto coupling" and the Patent Owner's apparent broad interpretation of the "by a gap sized for passage of the blood …" term.

iii. **Ground 3:** Akamatsu-1999 alone applies my narrower interpretation of "magneto coupling" and the Patent Owner's apparent broad interpretation of the "by a gap sized for passage of the blood …" term.

iv. **Ground 4:** Schima in view of Akamatsu-1999 applies my narrower interpretation of "magneto coupling" and my narrower interpretation of the "by a gap sized for passage of the blood …" term.

147. The table below also summarizes how the grounds correspond with the possible claim interpretation:

<table>
<tr><td colspan="2" rowspan="2">Summary of four permutations of claim interpretations:</td><td colspan="2">"magneto coupling"</td></tr>
<tr><td>Plain and ordinary meaning (i.e., rotating permanent magnets)</td><td>PO's apparent construction (includes drive by magnetic levitation)</td></tr>
<tr><td rowspan="2">"by a gap sized for passage of the blood "</td><td>Plain and ordinary meaning (i.e., hydrodynamic bearing)</td><td><u>Schima in view of Akamatsu-1999</u></td><td><u>Wampler-169</u></td></tr>
<tr><td>PO's apparent construction (includes magnetic bearing)</td><td><u>Akamatsu-1999</u></td><td><u>Bourque-2001 alone or in view of Wampler-169</u></td></tr>
</table>

148. The table above is not meant to be limiting. For example, Wampler-169 is listed for the hydrodynamic bearing permutation, but it also discloses the use of magnetic bearings; Schima is listed for the drive by magneto coupling limitation but it also discloses use of drive by magnetic levitation; and other grounds also render obvious the alternative interpretations. Further, should any of the terms be interpreted broadly according to Patent Owner's interpretations, my narrower interpretations would in any event be included within those broader interpretations.

A. Ground 1: Wampler 169 Renders Obvious Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent

1. Claim 1

i. [1PRE] A system for assisting the blood circulation of a heart, comprising:

149. To the extent that the preamble is a limitation, Wampler-169 discloses "*a system for assisting blood circulation of a* ***heart***."

150. For example, Wampler-169 seeks to address the problems faced by patients with "left ventricular heart failure" who "could benefit from cardiac transplantation," but are unable to receive a donor. Wampler-169 states that "if a left ventricular assist device ("LVAD") were available for chronic use, many of these patients could be returned to prolonged and productive lives." Ex.1008, [0003]. Therefore, Wampler-169 discloses a "left ventricular assist device ('LVAD')" which

uses an "improved rotary blood pump" that uses "passive, magnetic radial bearings to maintain an impeller and its support shaft for rotation about an axis." Ex.1008, [0007]. Further, Wampler-169 discloses that the "invention relates to the field of blood pumps" and in particular, "pertains to continuous flow pumps of rotary design, suitable for permanent implantation in humans for use as chronic ventricular assist devices." Ex.1008, [0002].

151. Accordingly, Wampler-169 discloses "*a system for assisting the blood circulation of a* ***heart***."

ii. [1A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart

152. Wampler-169 discloses "***a heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** *and having a suction end insertable into* ***a ventricle of the heart***."

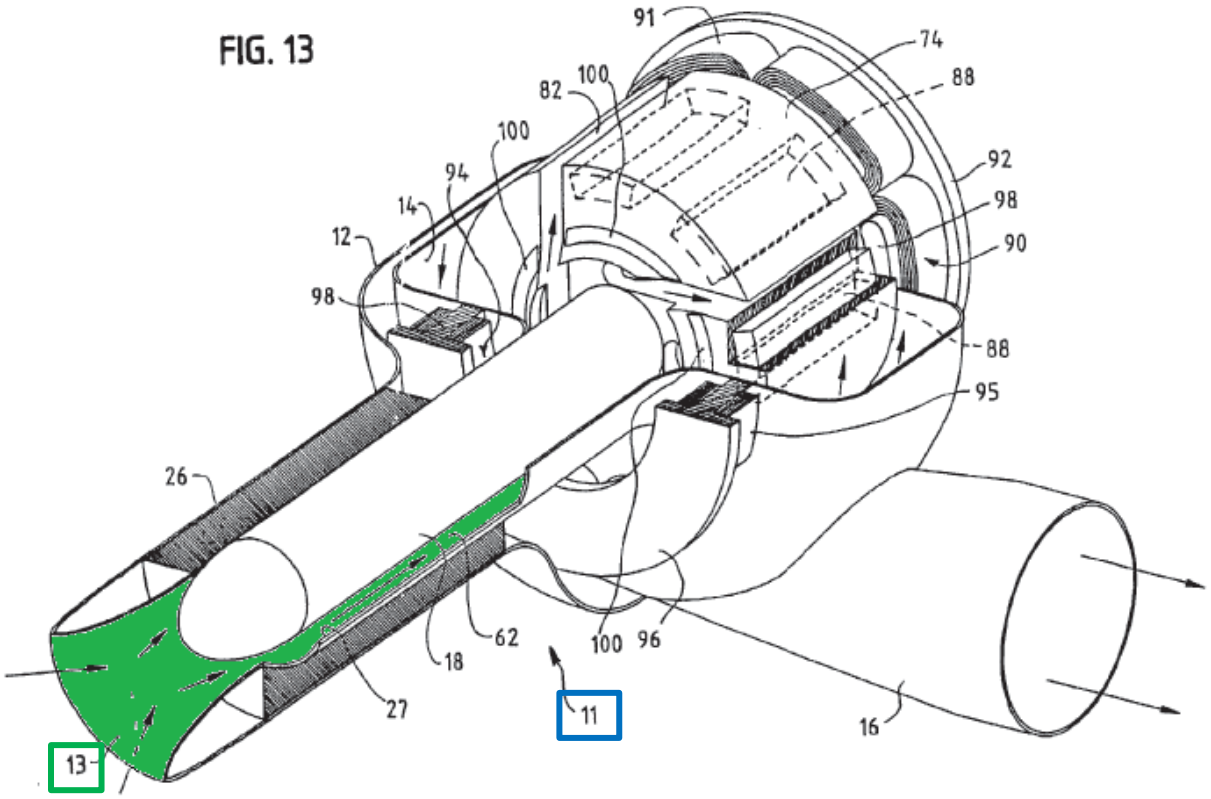
153. The 077 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device deliverable to the heart" includes "an inflow cannula…inserted into a left ventricle of a patient's heart." *See* Ex.1019, at pp. 3 (Complaint, Ex. 13). For the

purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

154. Accordingly, Wampler-169 discloses the "anatomical placement of the pump 11," in the "human heart 63," which "includes a left ventricle 64 and an aorta." Wampler-169, [0075]. Further, the pump 11 includes an "inlet tube 13" that "serves as the inflow cannula and is placed into the apex of the left ventricle 64."[17] Ex.1008, [0075]; *see also* Ex.1008, Abstract ("An implantable rotary sealless blood pump is provided. The pump includes a housing having ***an inlet tube*** on one end and an impeller casing on the other end."), [0050] ("Turning now to FIGs. 1-8 of the drawings, a sealless rotary blood pump 11 includes a housing 12, having an ***elongated inlet tube 13*** and an impeller casing or volute 14."), [0080] ("Referring to FIGS. 11, 11*a*, 12, 13 and 14, the blood pump 11' shown therein is similar in many respects to blood pump 11 illustrated in FIGS. 1-8, and includes housing 12 having an elongated inlet tube 13 and a scroll-shaped impeller casing or volute 14.").

[17] I note that paragraph [0075] of Wampler 169 denotes the "inlet tube" with the reference number 16. However, the "inlet tube" is denoted elsewhere in the reference with the number 13, while the "discharge tube" is denoted with the number 16. Therefore, I understand the reference to "inlet tube 16" in paragraph [0075] to be a drafting error, and will refer to the inlet tube as "inlet tube 13."

155. Thus, Wampler-169 discloses **a heart assist pump device** (e.g., "blood pump 11," Ex.1008, [0080]) deliverable to the **heart** (e.g., "human heart 63," Ex.1008, [0075]) and comprising: an **inflow tube defining a blood inflow path and having a suction end** (e.g., "inlet tube 13" which "serves as the inflow cannula," Ex.1008, [0075], [0080]) insertable into **a ventricle of the heart** (e.g., "inlet tube [13] ... is placed into the apex of the left ventricle 64," Ex.1008, [0075]). Figure 13 (annotated) of Wampler-169 illustrates a fragmentary, cross-sectional view of an embodiment of pump 11 (**blue**), which includes an inlet tube 13 (**green**) having a suction end:



Ex.1008, Fig. 13 (annotated); *see also* Fig. 1, 2, 4, 5.

156. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the suction end of the inlet tube 13 (**green**) of the pump 11 (**blue**) implanted within the left ventricle 64 (**red**) of the heart:

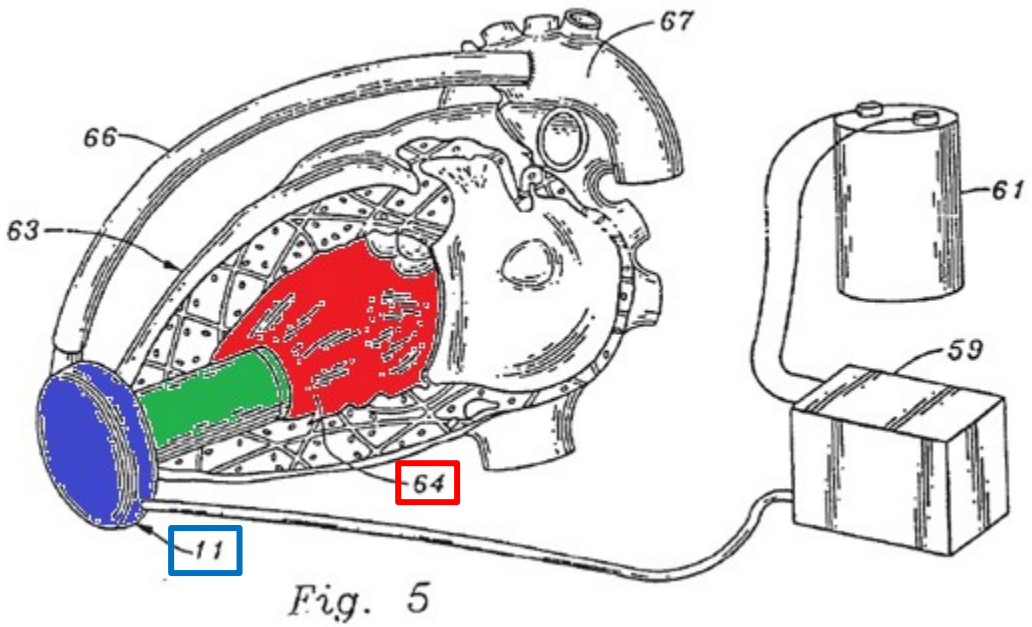


Fig. 5

Ex.1008, Fig. 5 (annotated).

157. Accordingly, Wampler-169 discloses "***a heart assist pump device*** ("blood pump 11"") *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path and having a suction end insertable*** ("inlet tube 13") *into* ***a ventricle of the heart*** ("placed into the apex of the left ventricle 64").

iii. [1B] a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle

158. Wampler-169 discloses that "*a **magnetically driven rotor assembly** configured to be axially aligned with the **inflow tube** and to be spaced apart from the suction end when the **suction end of the inflow tube** is inserted into the **ventricle**.*"

159. The pump 11 described in Wampler-169 includes a "**magnetically driven rotor**" that is spaced apart from the suction when the suction end of the inflow tube is inserted into the ventricle. Wampler-169 describes that the pump 11 includes "a pump rotor 17" within "housing 12" that includes "an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74." Ex.1008 at [0081]; *see also* Ex.1008, [0051]. The "[r]otor 17 is mounted for rotation about an longitudinal axis which extends both through shaft 18 and impeller 74." Ex.1008, [0051].

160. An impeller is a commonly used type of rotor used in a centrifugal pump, such as the "centrifugal pump" described in Wampler-169. Ex.1008, [0012] ("A centrifugal pump impeller is attached to an impeller support shaft, or spindle, to form the pump rotor."); *see also* Ex.1008, [0051] ("It should be noted that the

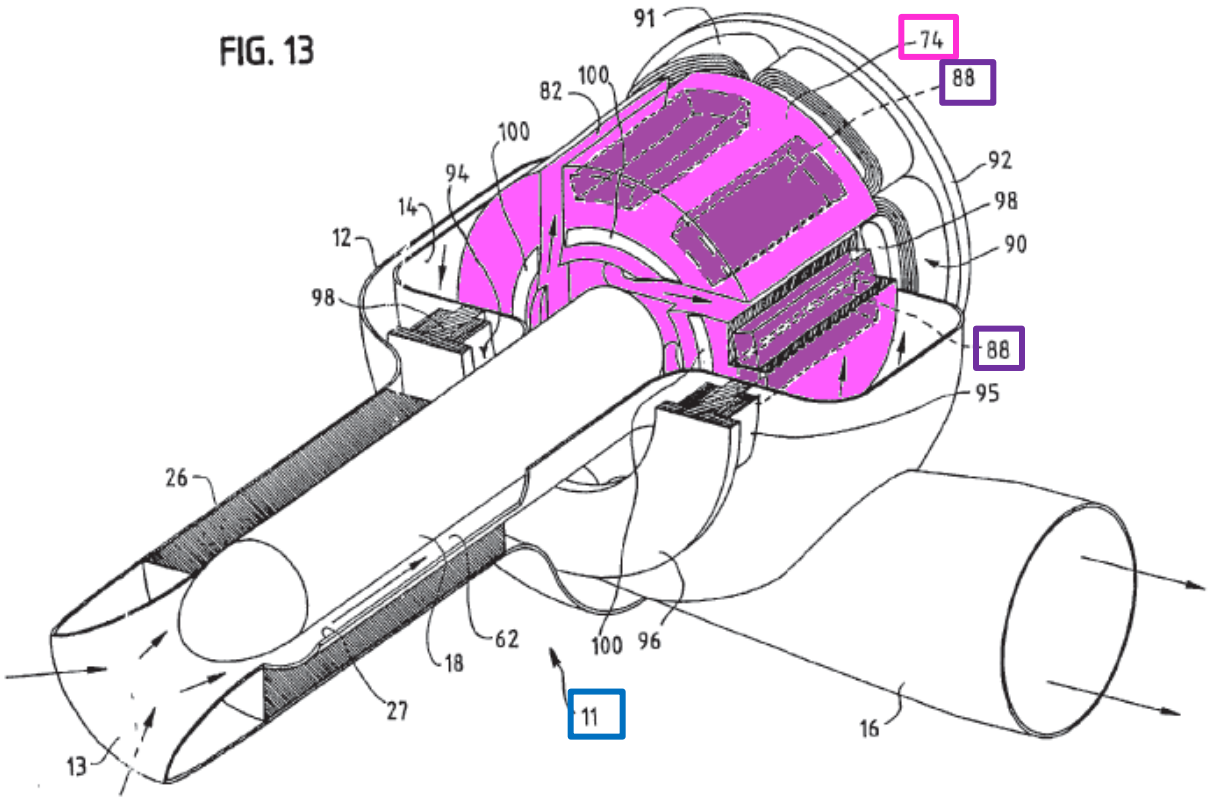
preferred embodiment disclosed herein includes an impeller and a casing of centrifugal design."), [0065] ("It is generally preferable in a large centrifugal pump, to have a substantial number of thin, sharp impeller blades with relatively large voids or passages, between the blades, for the passage of low viscosity liquid."). I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the "rotor" of the "HeartMate 3" to the "magnetically driven rotor" element recited in Claim 1. Ex.1019, at pp. 5-6 (Complaint, Ex. 12). For the purposes of my analysis, I map the limitation of a "magnetically driven rotor" to the "impeller 74" of the embodiment of the rotor 17 described in Figure 11 of Wampler-169 in the same way.

161. Thus, based on the disclosures above, the "impeller 74" of the rotor 17 of pump 11 described in Wampler-169 is a "**rotor**."

162. Wampler-169 further discloses that the "impeller 74" of the rotor 17 is "**magnetically driven**" as recited in claim 1. For example, Wampler-169 discloses that the "thick impeller blades are also used advantageously to house magnets used in the pump drive system. Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing." Ex.1008, [0018]; *see also* Ex.1008, [0019] ("In certain embodiments of the

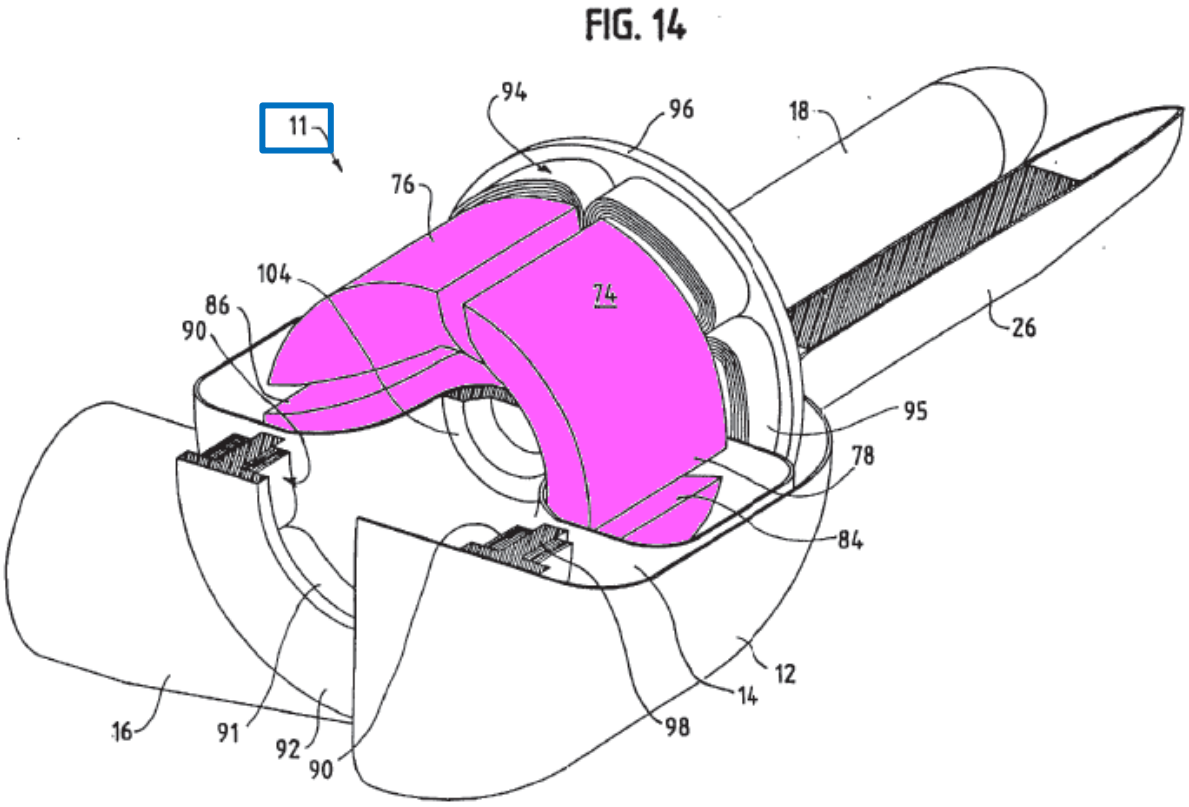
invention, the motor includes a plurality of permanent magnets carried by the impeller and a motor stator including an electrically conductive coil located with the housing."). As detailed below with respect to element [1C], these permanent magnetic segments are **magnetic pieces 88**, which are rigidly coupled and axially adjacent **impeller 74**.

163. Thus, the **impeller 74** together with the **magnetic pieces 88** described in Wampler-169 are a **magnetically driven rotor assembly** because together they form a rotor driven by the force generated by the electromagnetic field created between the "permanent magnetic segments imbedded within each impeller blade sector" and the "circular electromagnetic stator" of the motor. *See infra* Elements [1I] and [1E]; Ex.1008, [0070], [0072], [0080], [0083]-[0085]. Figure 13 of Wampler-169 depicts a perspective view of the impeller 74 (**pink**) being rigidly coupled to the magnetic pieces 88 (**purple**) removed from the pump 11 (**blue**), partially broken for illustrative purposes:



Ex.1008, Fig. 4, *see also* Figs. 1, 2, 3, 5.

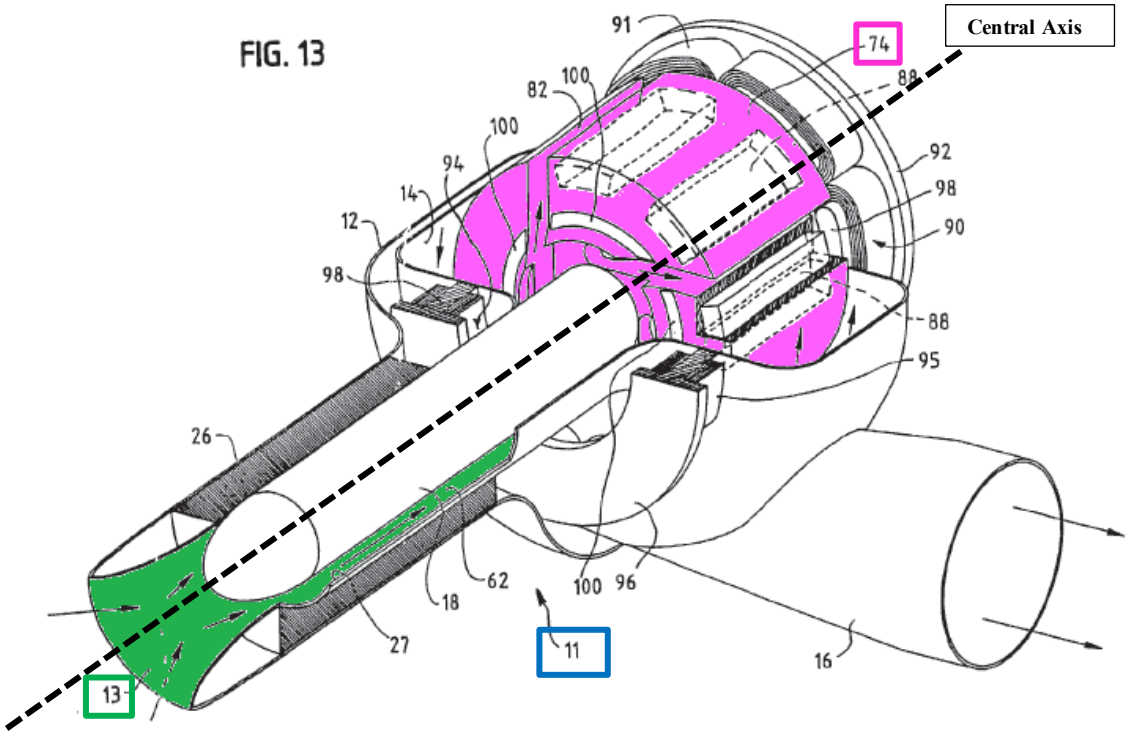
164. As another example, Figure 14 (annotated) shows a rear perspective view of the same embodiment of pump 11 (**blue**), which includes "impeller 74" (**pink**) of the rotor 17:



Ex.1008, Fig. 14 (annotated), *see also* Fig. 6, 7, 8.

165. For components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis") in space. The pump 11 described in Wampler-169 has a central axis that is configured in axial alignment with the **inflow tube** (e.g., "inlet tube 13" which "serves as the inflow cannula," Ex.1008, [0075], [0080]) so as to provide the flow of blood to the **magnetically driven rotor assembly** (e.g., "impeller 74" of the rotor 17, Ex.1008, [0081]). For example, Figure 13 (annotated) of Wampler-169

illustrates the alignment of the impeller 74 (**pink**) of the rotor 17 and the inlet tube 13 (**green**) of pump 11 (**blue**) along a central axis and the flow path of blood from the left ventricle the heart (indicated by black arrows entering the inlet tube):

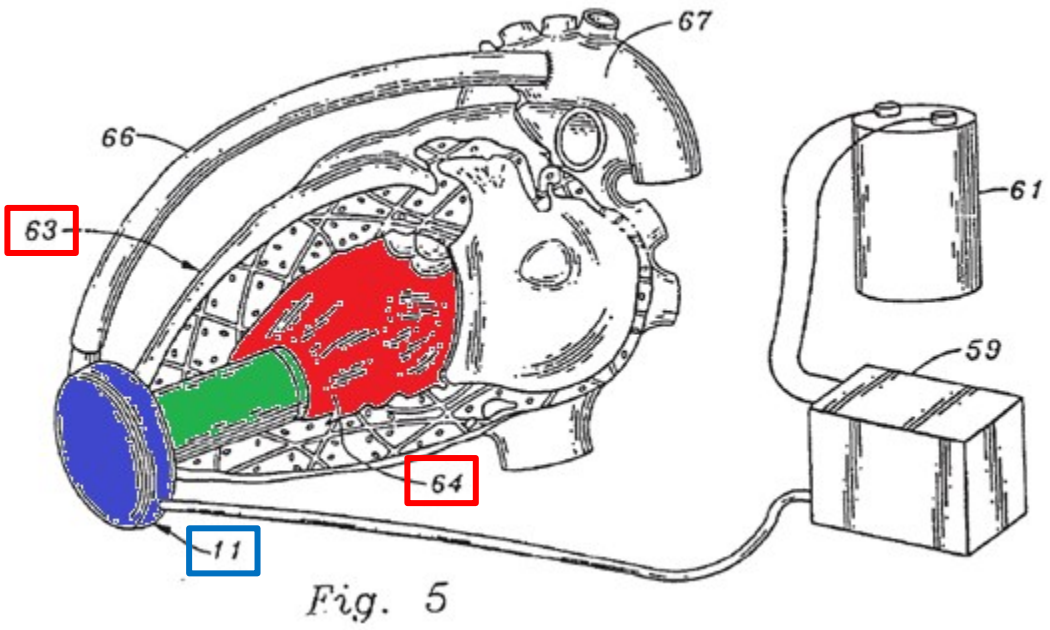


Ex.1008, Fig. 3 (annotated).

166. Wampler-169 discloses that "[o]wing to the **axial inflow** and radial outflow of the pump, a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076]. Indeed, the pump described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal

force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

167. Wampler-169 further discloses that the ***magnetically driven rotor assembly*** is "*spaced apart from the suction end when the suction end of the* ***inflow tube*** *is inserted into the* ***ventricle***." The impeller 74 of the rotor 17 of the pump 11 described in Wampler-169 is positioned outside the left ventricle of the heart. Ex.1008, [0076]. For example, Figure 5 (annotated) illustrates the positioning of the pump 11 (**blue**), in which the impeller 74 of the rotor is located (see above), outside the left ventricle of the heart (**red**):



Ex.1008, Fig. 5 (annotated).

168. Accordingly, Wampler-169 discloses that "*a **magnetically driven rotor assembly*** ("impeller 74") *configured to be axially aligned with the **inflow tube*** ("inlet tube 13") *and to be spaced apart from the suction end when the **suction end of the inflow tube** is inserted into the **ventricle***."

iv. [1C] the magnetically driver rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor

169. Wampler-169 discloses the **magnetically driven rotor assembly** "*comprising a **first magnetic device** that is rigidly coupled to and axially adjacent to a **rotor***"

170. As discussed above with respect to element [1B], the magnetically driven rotor assembly **rotor 17** comprises **magnetic pieces 88** which are rigidly coupled and axially adjacent **impeller 74**.

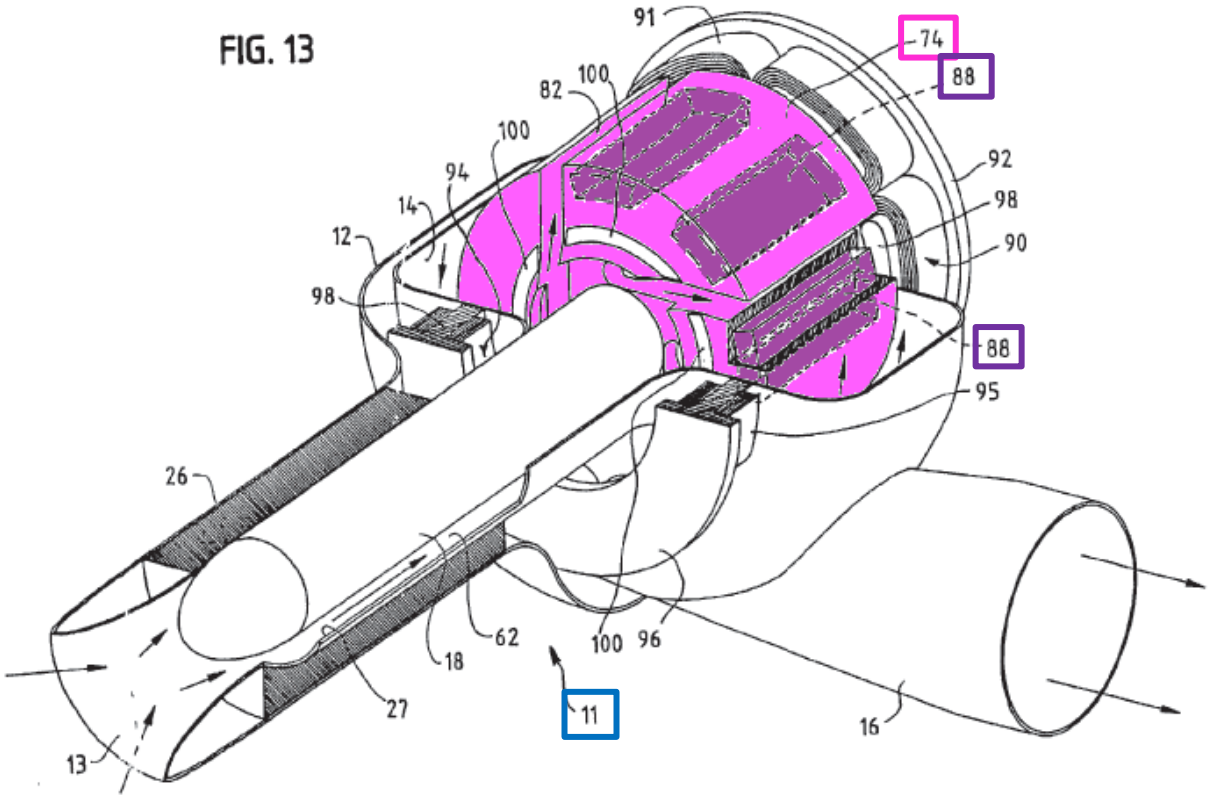
171. As will be discussed with respect to elements [1G] and [1J], "segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56," which includes "windings 57" that are "energized by the electrical output of controller 59 to produce an electromagnetic field." Ex.1008, [0070], [0072]; *see infra* Sections X.A.1.viii and X.A.1.xi. "This field is concentrated by pole pieces 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion." Ex.1008, [0072]; *see also* Ex.1008, [0073] ("Motor 53, with

windings 57 and pole piece 58, together with magnets 54, function not only to transmit torque but also provide a restoring radial magnetic force that acts as a radial bearing.").

172. In the embodiment described with respect to Figures 11-14, a "dual stator design" is used wherein a "first motor stator 90" having "conductive coils or motor windings 91, is located at the rear of impeller 74" and a "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74." Ex.1008, [0084]. Wampler-169 states that the "dual stator design is adapted to provide system redundancy for a fail safe mode, since each stator can be made to operate independently of the other in the case of emergency." Ex.1008, [0088].

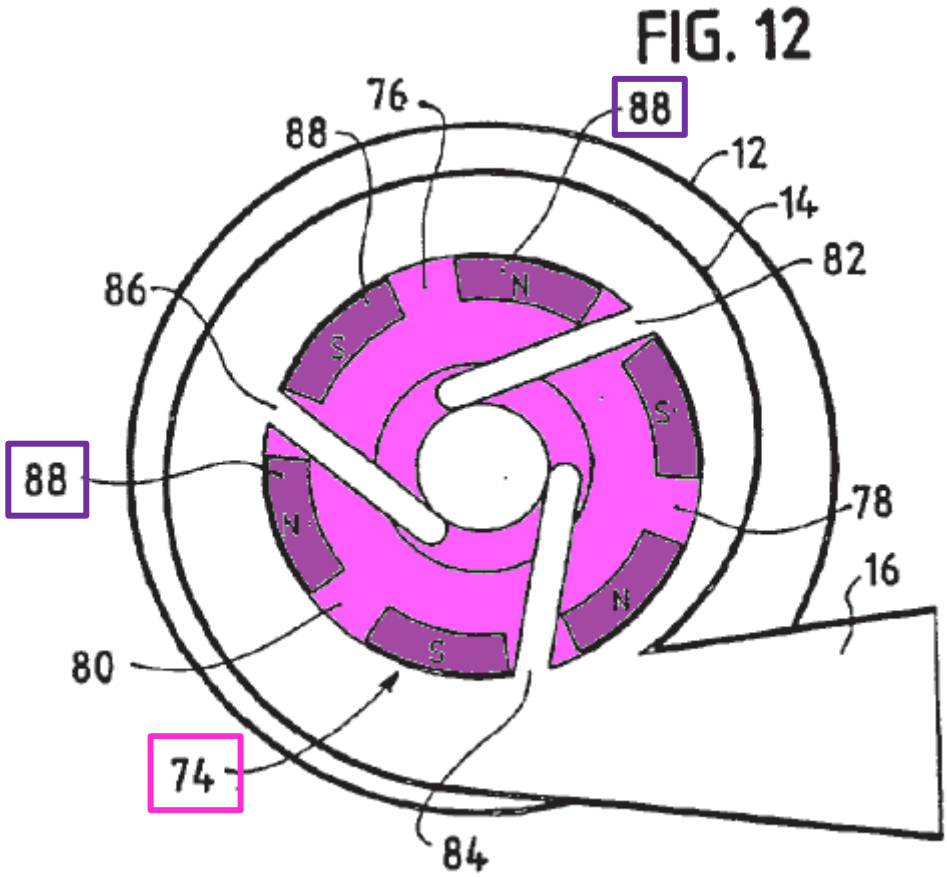
173. Thus, for the purposes of my analysis, I understand the interaction between the "magnetic segments 54" / "magnetic pieces 88" and the "motor stator 56" / "motor stators 90 and 94" to drive rotation of the impeller 74, is the same between the two embodiments. *See infra* element [1G], Section X.A.1.viii.

174. Figure 13 of Wampler-169 depicts a perspective view of the impeller 74 (**pink**) being rigidly coupled to the magnetic pieces 88 (**purple**) removed from the pump 11 (**blue**), partially broken for illustrative purposes:



Ex.1008, Fig. 4, *see also* Figs. 1, 2, 3, 5.

175. Figure 12 (annotated) of Wampler-169 illustrates a cross-sectional end view of the impeller 74 (**pink**) having the sealed magnetic pieces 88 (**purple**) with the casing removed for clarity:



Ex.1008, Fig. 12 (annotated); *see also* Figs. 6, 13, 14, 16.

176. Regarding the **first magnetic device** being axially adjacent the **rotor**, Wampler-169 discloses that "[r]otor 17 is mounted for rotation about an longitudinal axis which extends both through shaft 18 and impeller 74." Ex.1008, [0081]; *see*

also Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a rotational axis."), [0052] ("The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its ***longitudinal axis***."). Further, the described pump implements an "axial inflow and radial outflow," so that "a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

177. As demonstrated above in Figures 13 and 16 (annotated) of Wampler-169 the impeller 74 (**pink**) and embedded magnetic pieces 88 (**purple**) are axially adjacent along the central (or longitudinal) axis (**black**).

178. Accordingly, Wampler-169 discloses "*the **magnetically driven rotor assembly*** ("rotor 17") *comprising a **first magnetic device*** ("magnetic pieces 88") *that is rigidly coupled to and axially adjacent to a **rotor*** ("impeller 74")."

v. [1D] [the rotor] having guide surfaces to produce centrifugal flow components

179. Wampler-169 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

180. Wampler-169 discloses that the "impeller 74" of the rotor 17 is a "centrifugal pump impeller" that "includes a plurality of large blade sectors 49."

Ex.1008, [0012], [0064]. "When blood flows axially into the leading edges of impeller blades it tends to be damaged by the mechanical action and turbulence associated with the impeller blades. Thus, one of the design considerations of the present invention is to reduce such hemolysis, by minimizing the number of impeller blades and leading edges." Ex.1008, [0064]. Further, "[b]y increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the area of working surface of the blades and the volume of the passageway is increased." Ex.1008, [0068].

181. Each of the blade sectors 49 of the impeller 74 is a "guide surface," which serves to direct the flow of blood within the centrifugal pump to the outflow subassembly. For example, Wampler-169 discloses that [r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074].

182. Indeed, the pump 11 described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, the

production of centrifugal flow components by the components of the impeller are a characteristic feature of a centrifugal pump.

183. As will be discussed with respect to element [1G], Wampler-169 discloses that the **magnetically driven rotor** (e.g., "impeller 74") is rotated via a magneto coupling between the "magnetic pieces 88" imbedded in the impeller 74. *See supra* Section X.A.1.viii.

184. Wampler-169 further discloses that the "impeller 74" of the rotor 17 is a "centrifugal pump impeller" that "includes a plurality of large blade sectors 49." Ex.1008, [0012], [0064]. "When blood flows axially into the leading edges of impeller blades it tends to be damaged by the mechanical action and turbulence associated with the impeller blades. Thus, one of the design considerations of the present invention is to reduce such hemolysis, by minimizing the number of impeller blades and leading edges." Ex.1008, [0064]. Further, "[b]y increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the area of working surface of the blades and the volume of the passageway is increased." Ex.1008, [0068].

185. Each of the blade sectors 49 of the impeller 74 is a "guide surface," which serves to direct the flow of blood within the centrifugal pump to the outflow subassembly. For example, Wampler-169 discloses that [r]otation of the rotor 17,

including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074].

186. Indeed, the pump 11 described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, the production of centrifugal flow components by the components of the impeller are a characteristic feature of a centrifugal pump.

187. Accordingly, Wampler-169 discloses the **rotor** ("impeller 74") "*having guide surfaces to produce centrifugal flow components*."

vi. [1E] the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube toward the rotor

188. Wampler-169 discloses that "*the **magnetically driven rotor assembly** being rotatable about a **central axis** within **a surrounding stationary housing** to act upon blood flowing from the **inflow tube** to the **rotor**.*"

189. As discussed above with respect to element [1B], the magnetically driven rotor assembly **rotor 17** comprises **magnetic pieces 88** which are rigidly coupled and axially adjacent **impeller 74**.

190. Further, Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74"), [0050].

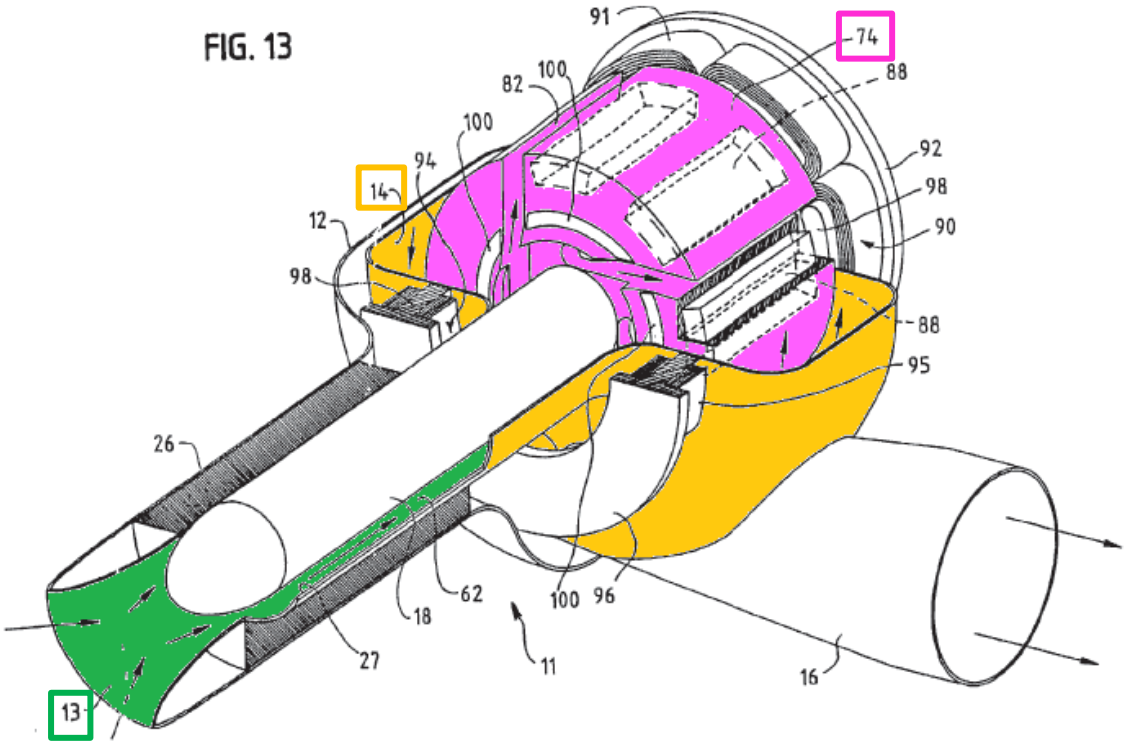
191. Thus, the "casing 14" of the pump 11 is a **surrounding stationary housing** which houses a **magnetically driven rotor assembly** (*e.g.*, "impeller 74" and "magnetic pieces 88" of the rotor 17, Ex.1008 at [0081]).

192. Wampler-169 discloses that "[r]otor 17 is mounted for rotation about a longitudinal axis which extends both through shaft 18 and impeller 74." Ex.1008, [0081], [0051]. Wampler-169 further discloses the flow path of blood through the

pump as follows:[18] "Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing an [sic] into the user's cardiovascular system." Ex.1008, [0074], *see also* Abstract ("A rotor is mounted for rotation within the housing…").

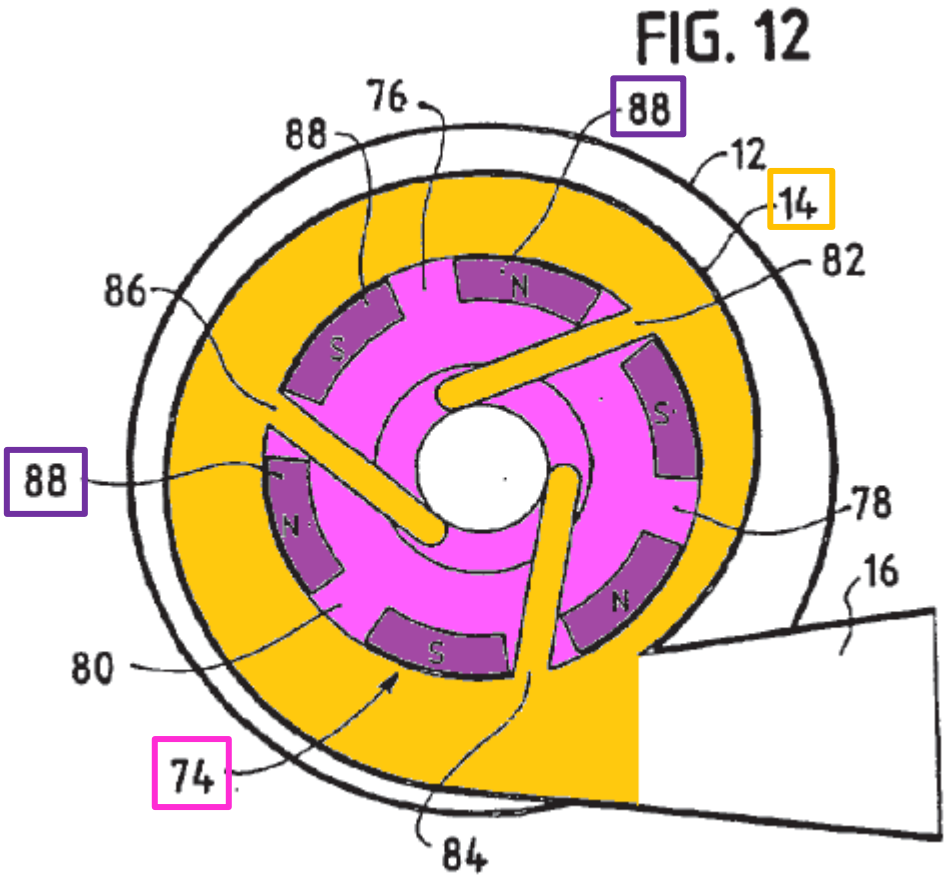
193. Figure 13 (annotated) illustrates the impeller 74 (**pink**) of the rotor 17 rotatable within the casing 14 (**orange**) of the pump 11 to act upon blood flowing (black arrows) from the inlet tube 13 (**green**) toward the impeller:

[18] Note, while this flow path is described with respect to the embodiment of the pump 11 described with respect to FIGs. 1-8, Wampler 169 states that the "blood pump 11'" shown in FIGs. 11, 11*a*, 12, 13, and 14 "is similar in many respects to blood pump 11 illustrated in FIGS. 1-8," including with respect to the flow path of blood. Ex.1006, [0080]; *see also* Ex.1006, [0103] ("Various elements from the FIGS. 1-8 embodiment can be used in the FIGS. 11-20 embodiments.").



Ex.1008, Fig. 13 (annotated).

194. Figure 12 (annotated) of Wampler-169 illustrates a cross-sectional end view of the impeller 74 (**pink**) having the sealed magnetic pieces 88 (**purple**) within the casing 14 (**orange**):



Ex.1008, Fig. 12 (annotated).

195. Accordingly, Wampler-169 discloses "*the* ***magnetically driven rotor assembly*** ("rotor 17") *being rotatable about a* ***central axis*** *within* ***a surrounding stationary housing*** ("casing 14") *to act upon blood flowing from the* ***inflow tube*** ("inlet tube 13") *to the* ***rotor*** ("impeller 74")."

vii. [1F] while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood

196. Wampler-169 discloses that "*the **magnetically driven rotor assembly** is entirely spaced apart from the **stationary housing** by a gap sized for passage of the blood*."

197. As discussed above with respect to element [1B], the magnetically driven rotor assembly **rotor 17** comprises **magnetic pieces 88** which are rigidly coupled and axially adjacent **impeller 74**.

198. In addition, Wampler-169 discloses that in the embodiments described with respect to Figures 11-14, "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Referring to FIGS. 11 and 11*a* in particular, hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102 and 103 are illustrated." Ex.1008, [0089]. Note that these embodiments do not include the mechanical "thrust bearings" included in the embodiments, described with respect to Figures 1-8.

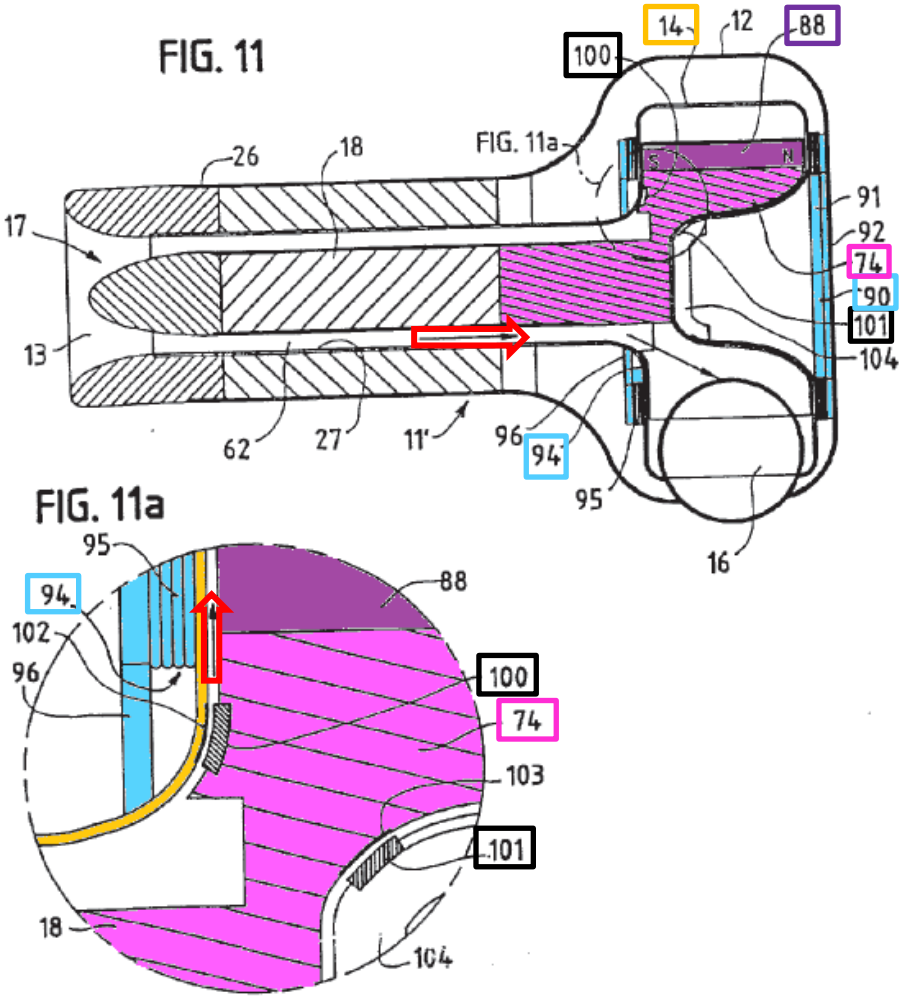
199. "The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the FIGS. 11 and 11 *a* embodiment, the raised pads 100

are carried by the impeller and the raised pads 101 are carried by a cup-shaped member 104 that is fastened to the casing." Ex.1008, [0091]. Such "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093].

200. In the embodiment described with respect to Figures 11-14, Wampler-169 teaches that "[t]he hydrodynamic bearings are formed by a raised pad ***spaced from a contact surface by the blood gap***. Although at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap ***which forces the raised pad and the contact surface apart***." Ex.1008, [0092].

201. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the hydrodynamic bearings formed by raised pads 100 and 101 (**black**), which serve to increase pressure within the bearing gap such that, once rotation of the impeller 74 (**pink**), the blood flowing (**red** arrow)

forces the raised pad and the contact surface apart: begins magneto coupling (described below with respect to element [1G]) between "magnetic pieces 88" (**purple**) of the rotor assembly and the "motor stators 90 and 94" (**light blue**):



Ex.1008, Figs. 11 and 11*a* (annotated). Thus, "once rotation begins," "*the blood flowing*" produces a "fluid film…within the bearing gap" (Ex.1008, [0092]) that

causes the "**impeller**" and its "**magnetic pieces**" to be "suspended within the **housing**" (Ex.1008, [0013]).

202. Thus, the "magneto coupling" between the "magnetic pieces 88" of the impeller 74 and the "motor stators 90 and 94" drives rotation of the impeller 74 and when impeller 74 is rotated, the hydrodynamic bearing "forces the raised pad and the contact surface apart," such that the impeller 74 remains adjacent to and spaced apart from the casing 14 by the blood flowing from the inlet tube 13 to the discharge tube 16.

203. Accordingly, Wampler-169 discloses that "*the **magnetically driven rotor assembly*** ("impeller 74") *is entirely spaced apart from the **stationary housing*** ("casing 14") *by a gap sized for passage of the blood*."

viii. [1G] a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device

204. Wampler-169 discloses that "*a **second magnetic device** axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** via a magneto coupling with the **first magnetic device***."

205. As discussed above with respect to element [1B], the magnetically driven rotor assembly **rotor 17** comprises **magnetic pieces 88** which are rigidly coupled and axially adjacent **impeller 74**.

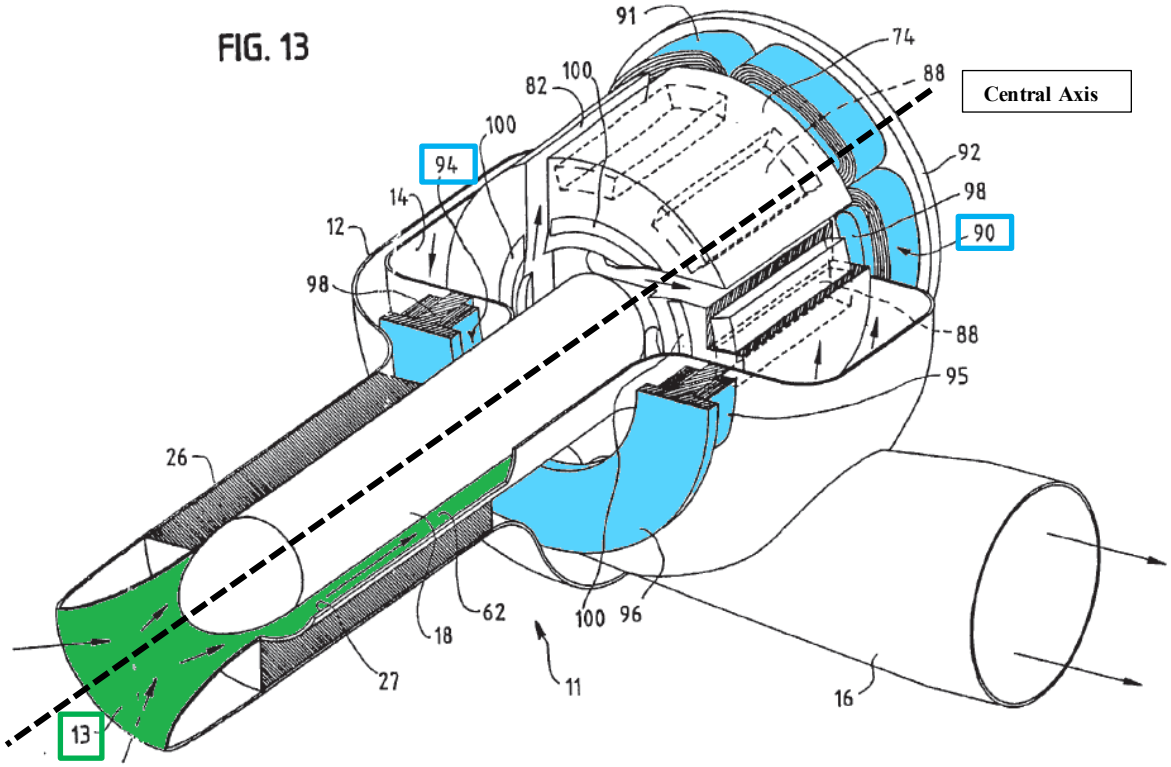
206. Also, as discussed above with respect to element [1B], for components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *Supra* Section X.A.1.iii. The **heart assist pump device** (*e.g.*, "blood pump 11," [0080]) described in Wampler-169 has an **inflow tube** (*e.g.*, the "inlet tube 13," Ex.1008, [0080]) that "serves as the inflow cannula" through which blood flows to the **rotor** (*e.g.*, "impeller 74" of the rotor, Ex.1008, [0081]), which is driven by the electromagnetic interaction between the **first magnetic device** (*e.g.*, the "magnetic pieces 88" embedded in the impeller 74, Ex.1008, [0070]) and the **second magnetic device** (*e.g.*, the "motor stators 90 and 94," Ex.1008, [0083]-[0084], Fig. 13).

207. Each of the impeller 74, the embedded magnetic pieces 88, and motor stators 90 and 94 described in Wampler-169 are axially aligned with the inlet tube 13 (e.g., "Rotor 17 is mounted for rotation about an longitudinal axis which extends both through shaft 18 and impeller 74," Ex.1008, [0081]). *See also* Ex.1008, [0013] ("Radial magnetic bearings of passive design, maintain the support shaft and the impeller about a rotational axis."), [0052] ("The pump 11 of the present invention

includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its longitudinal axis."). Further, the described pump implements an "axial inflow and radial outflow," so that "a 90 degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

208. Indeed, the pump 11 described in Wampler-169 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

209. For example, Figure 13 (annotated) illustrates the alignment of the "motor stators 90 and 94" (**light blue**) and the inlet tube 13 (**green**) of the pump 11 along a central axis (**black**):



Ex.1008, Fig. 13 (annotated); *see also* Figs. 3, 4, 7, 8*a*, 8*b*, 14.

210. Further, as discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a

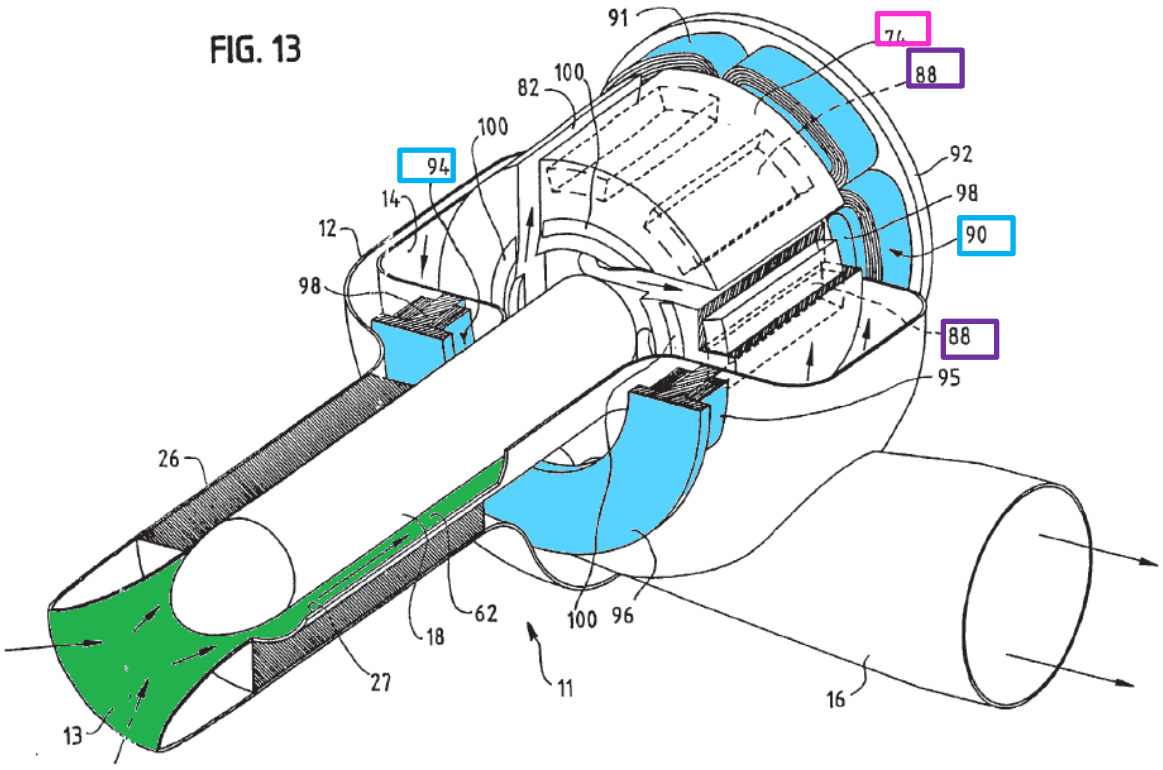
transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is correct. *See* Ex.1019.

211. Accordingly, based on the Patent Owner's understanding of the term, Wampler-169 describes a magneto coupling between the **second magnetic device** (e.g., the "motor stators 90 and 94" of the motor 53, Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]). For example, Wampler-169 discloses that "the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085].

212. The interaction between the motor stator is described with respect to the embodiment of Figures 1-8; the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. ***This field is concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17***, in a rotary fashion." Ex.1008, [0072]; *see also* Ex.1008, [0018] ("Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing."), [0085]. The interaction between the "motor stators 90 and 94" and the "magnetic pieces 88" described with

respect the embodiment of Figures 11-14 creates the same "torque drive" that is "imparted to the impeller."

213. Figure 13 (annotated) of Wampler-169 illustrates a perspective view of the pump 11 having the "motor stators 90 and 94" (**light blue**) being axially aligned with the "inlet tube 13" (**green**):

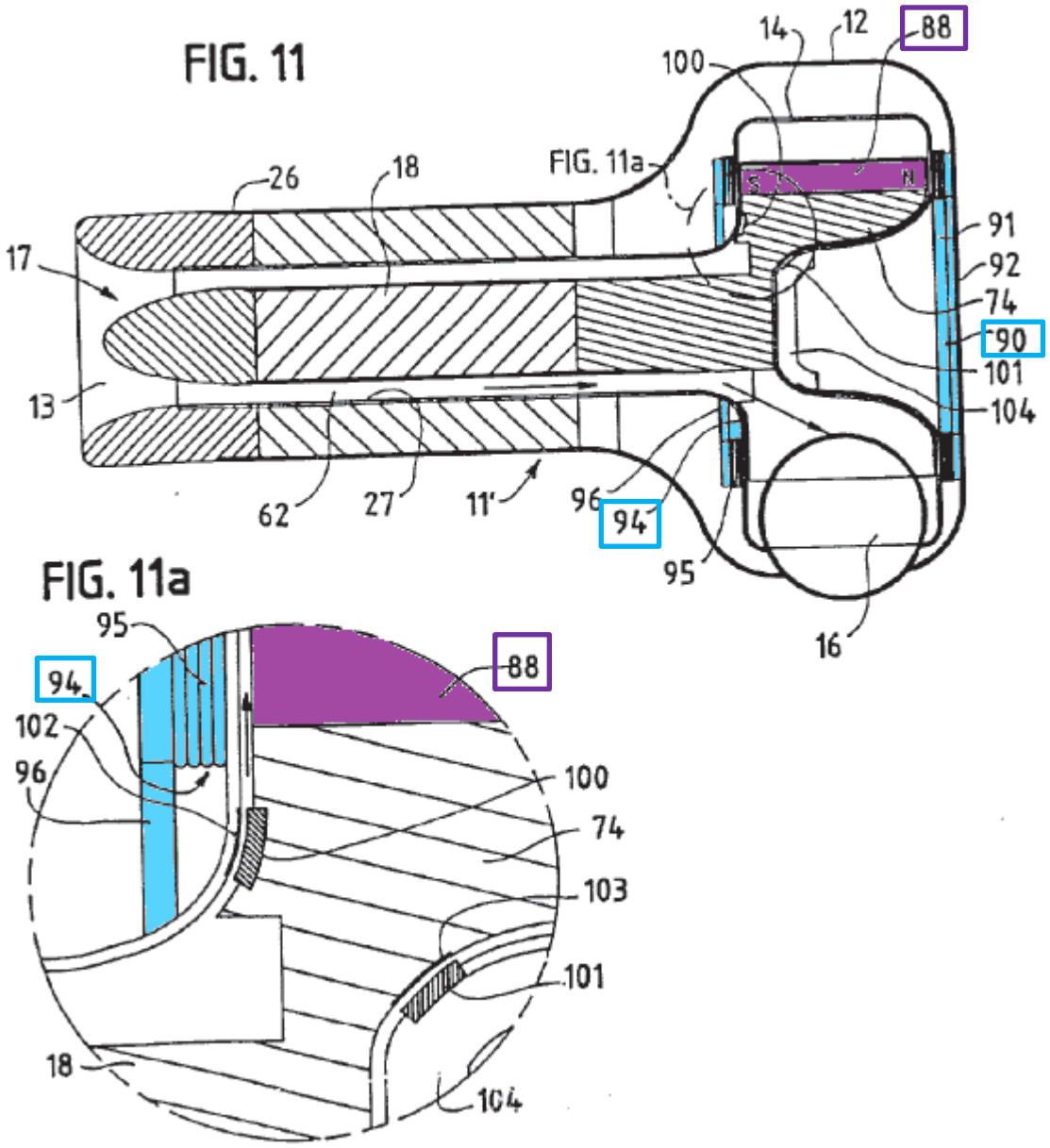


Ex.1008, Fig. 13, *see also* [0070] *see also* Figs. 4, 7, 8*a*, 8*b*.

214. Further, Wampler-169 describes the "[r]otation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62." Ex.1008, [0074]. Thus, the **second magnetic device** (*e.g.*,

"motor stators 90 and 94," Ex.1008, [0085]) is positioned to drive rotation of the **magnetically driven rotor assembly** (e.g., "impeller 74" and "magnetic pieces 88" of the rotor, Ex.1008, [0081]), via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]).

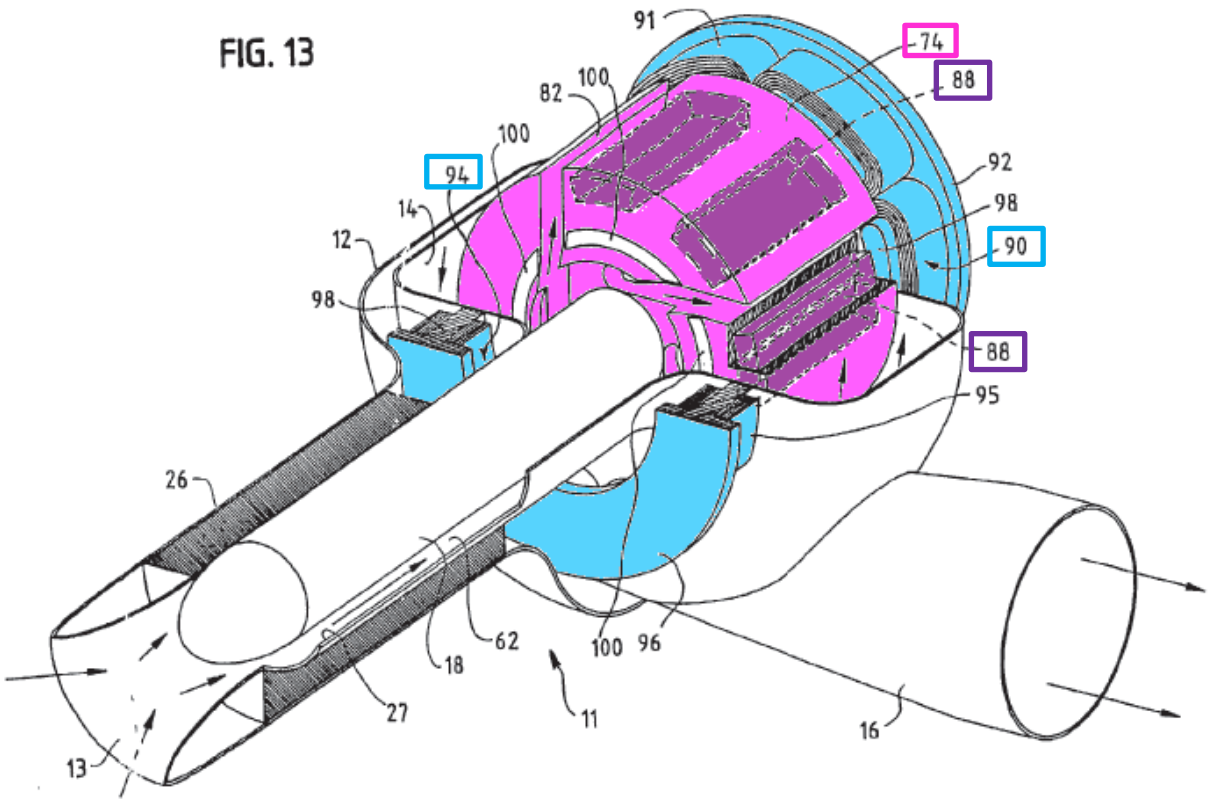
215. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the magneto coupling between "magnetic pieces 88" (**purple**) of the impeller and the "motor stators 90 and 94" (**light blue**):



Ex.1008, Figs 11 and 11*a*; *see also* Figs. 7, 8*a*, 8*b*.

216. In addition, Figure 13 (annotated) of Wampler-169 illustrates a perspective view of the pump 11 having the "motor stators 90 and 94" (**light blue**)

to drive the rotation of the "impeller 74" (**pink**) by the imbedded "magnetic pieces 88" (**purple**):



Ex.1008, Fig. 13

217. Accordingly, Wampler-169 discloses "*a* ***second magnetic device*** ("motor stators 90 and 94") *axially aligned with the* ***inflow tube*** ("inlet tube 13") *and positioned to magnetically drive rotation of the* ***magnetically driven rotor assembly*** ("impeller 74") *via a magneto coupling with the* ***first magnetic device*** ("magnetic pieces 88")."

ix. [1H] while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly

218. Wampler-169 discloses that the **second magnetic device** is positioned according to element [1H] "*while being spaced apart and sealed from both the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly**.*"

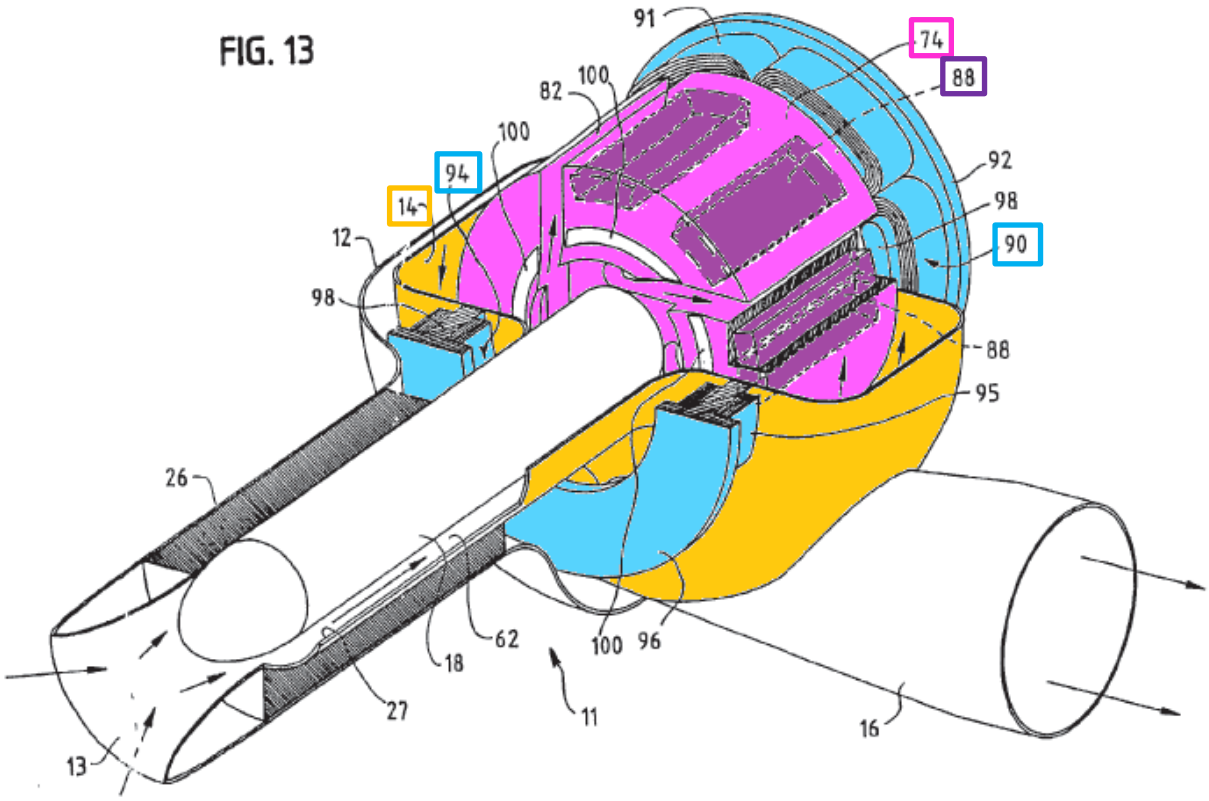
219. As discussed with respect to element [1E], Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74."), [0050].

220. Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that

each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "mounted on the outer surface of impeller casing 14"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

221. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008, [0005], [0018], [0019], [0070], [0072], [0073], 0074]. Thus, the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is spaced apart and sealed from both the **rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller, Ex.1008, [0080]).

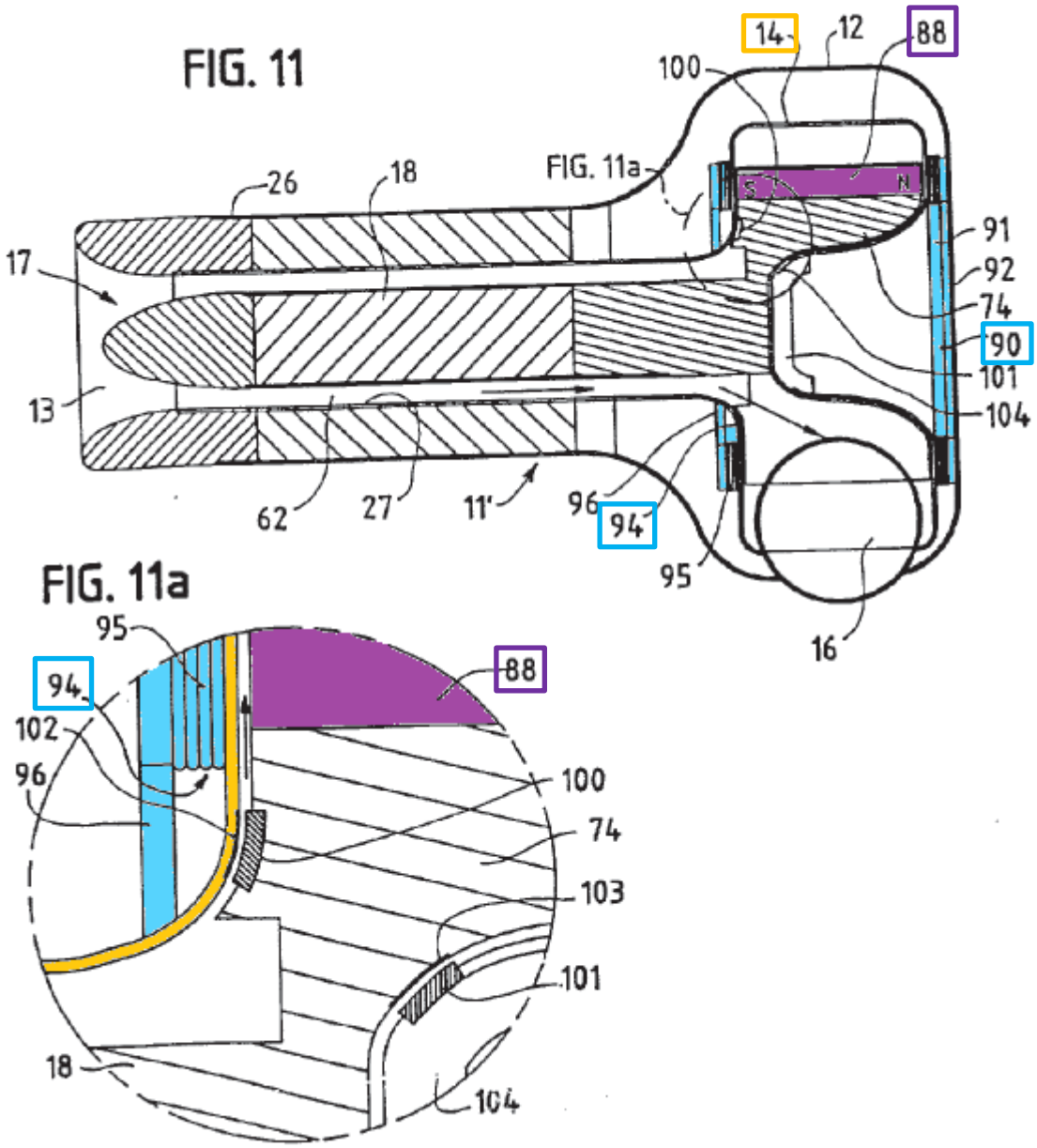
222. Figure 13 (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) being spaced apart and sealed from the "impeller 74" (**pink**) and "magnetic pieces 88" (**purple**) by the casing 14 (**orange**):



Ex.1008, Fig. 13 (annotated). Wampler-169 discloses that blood enters "the interior of the casing 14" and is "expelled from the casing" via a "discharge tube 16," indicating that the interior of the casing 14 is sealed from the exterior of the casing 14. Ex.1008, [0074]. In any event, it would have been obvious "in actual practice" that "a thin-walled non-magnetic jacket be placed over these portions," such as the casing or magnetic elements, "to prevent contact between the magnets and the blood ['*sealed…by at least one sealing wall*']." Ex.1008, [0057]. A POSITA would have been motivated to do so because, as Wampler-169 itself explains, "[s]uch contact, if

it were allowed, would likely cause an undesirable chemical reaction, to the determinant of the blood. Ex.1008, [0057].

223. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the "magnetic pieces 88" (**purple**) of the impeller being spaced apart and sealed from the "motor stators 90 and 94" (**light blue**) by the casing 14 (**orange**):



Ex.1008, Figs. 11, 11*a*; *see also* Figs. 7, 8*a*, 8*b*.

224. Accordingly, Wampler-169 discloses that the **second magnetic device** ("motor stators 90 and 94") is positioned according to element [1H] "*while being spaced apart and sealed* (by the "casing 14") *from both the* ***rotor*** ("impeller 74")

*and the **first magnetic device*** ("magnetic pieces 88") *of the **magnetically driven rotor assembly***."

x. [1I] the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor

225. Wampler-169 discloses "*the **second magnetic device** being positioned axially spaced apart from the guide surfaces of the **rotor***."

226. As discussed with respect to element [1D], the **rotor** comprises guide surfaces ("blade sectors 49") to produce centrifugal flow components.

227. As discussed with respect to element [1H], Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74."), [0050].

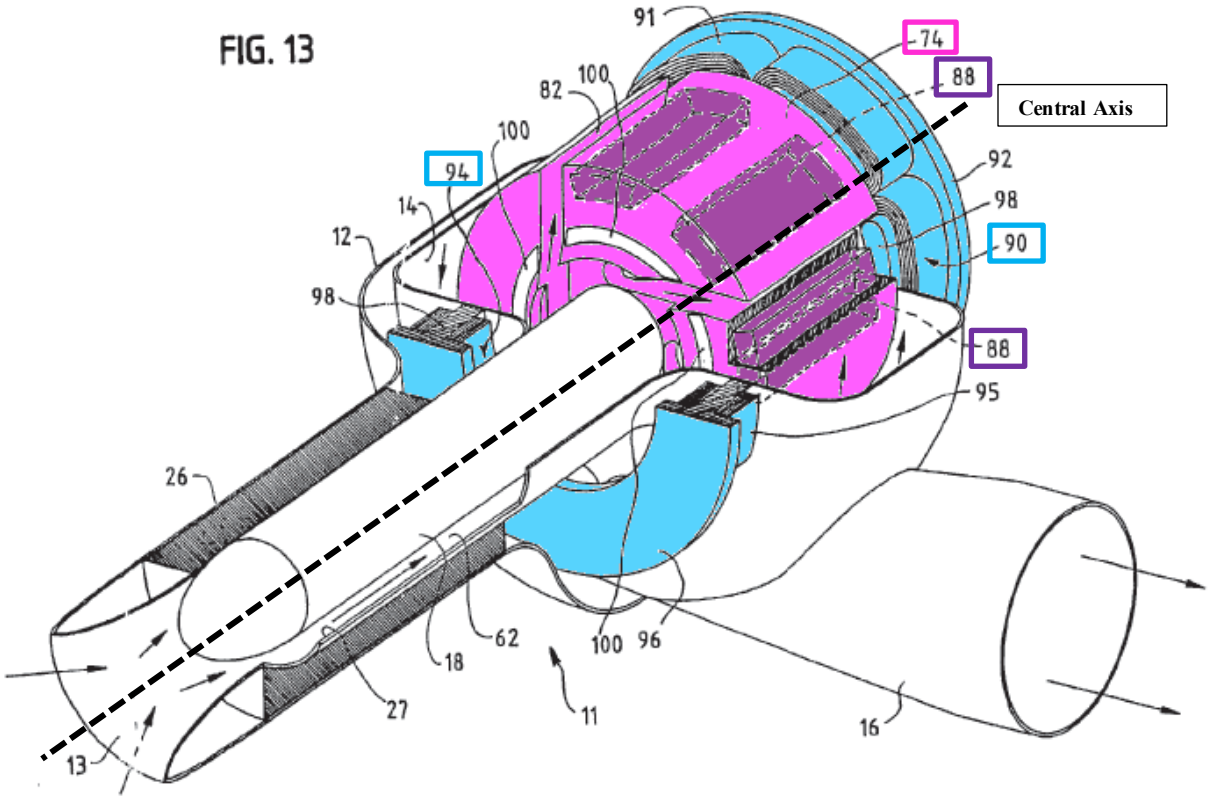
228. Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back iron 96

is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "mounted on the outer surface of impeller casing 14"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

229. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008, [0005], [0018], [0019], [0070], [0072], [0073], 0074]. Thus, the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is spaced apart and sealed from the **rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]).

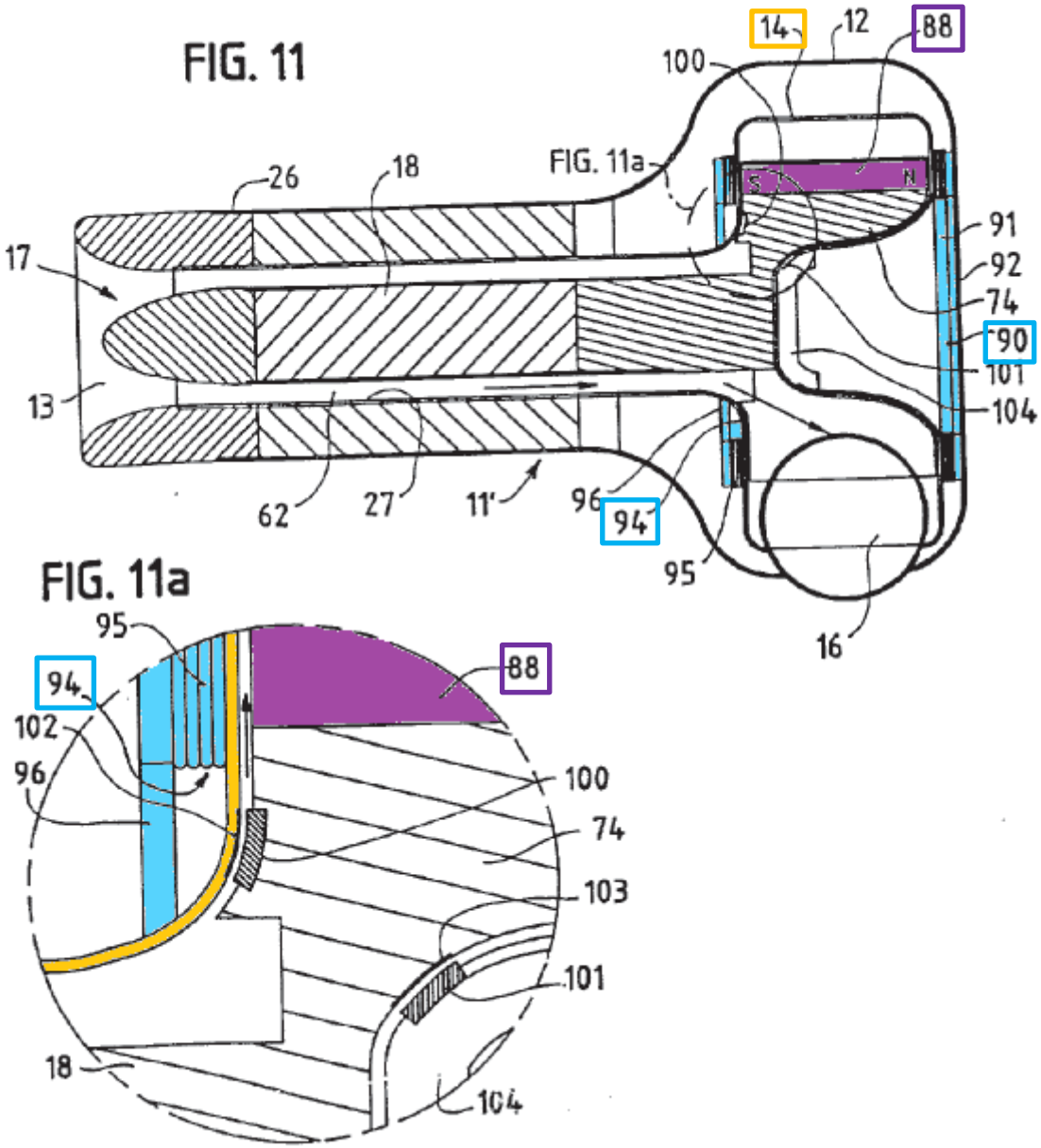
230. Figure 13 (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) being axially spaced apart from the

"impeller 74" (**pink**) and "magnetic pieces 88" (**purple**):



Ex.1008, Fig. 13.

231. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the "magnetic pieces 88" (**purple**) of the impeller being spaced apart and sealed from the "motor stators 90 and 94" (**light blue**) by the casing 14 (**orange**):



Ex.1008, Figs. 11, 11*a*; *see also* Figs. 7, 8*a*, 8*b*.

232. Accordingly, Wampler-169 discloses that "*the **second magnetic device*** ("motor stators 90 and 94") *being positioned axially spaced apart from the guide surfaces of the **rotor*** ("impeller 74")."

xi. [1J] a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly

233. Wampler-169 discloses "*a **blood outflow port** positioned radially adjacent the guide surfaces of the **rotor** such that, when the blood is driven by the **magnetically driven rotor assembly**, the blood exits the **surrounding stationary housing** in a direction substantially perpendicular to the **central axis** of the **magnetically driven rotor assembly***."

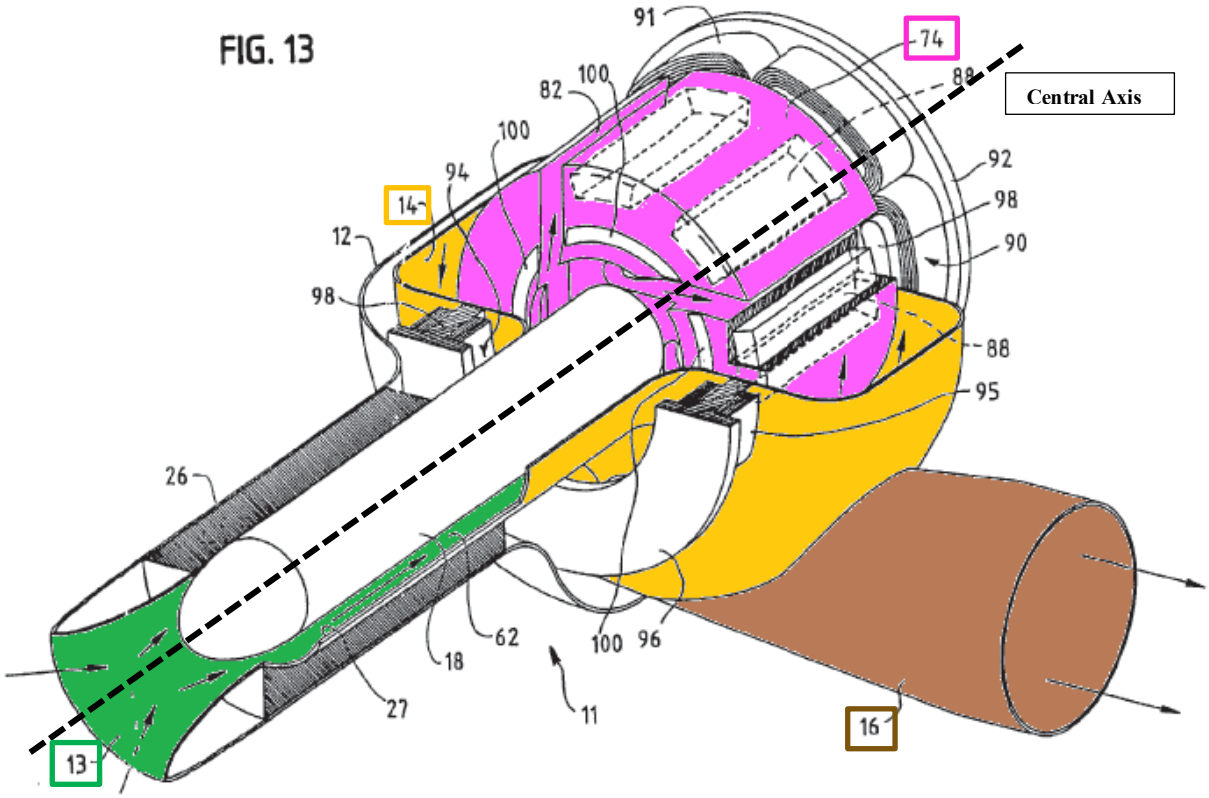
234. As discussed with respect to element [1E], Wampler-169 discloses that pump 11 includes a "discharge tube 16" which "extends through the housing to communicate with the interior periphery of casing 14." Ex.1008, [0080]; *see also* Ex.1008, [0050]. The discharge tube 16 "has a tangential orientation with respect to a radius of the casing, for effectively channeling the blood output from the pump." Ex.1008, [0080]; *see also* Ex.1008, [0074] ("Rotation of the rotor 17, including shaft 18 and impeller 19, ***causes blood to flow*** through inlet tube 13 in the direction of

arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14***. Discharge tube 16 allows the blood to be expelled from the casing an into the user's cardiovascular system***.").

235. Thus, the **blood outflow port** (e.g., "discharge tube 16") is radially adjacent to the guide surfaces (see element [1D]) of the **rotor** (e.g., the "impeller 74" of the rotor) such that blood driven by the impeller 19 is configured to exit the **surrounding stationary housing** (e.g., "casing 14") in a direction substantially perpendicular from the **inflow tube** (e.g., "inlet tube 13") and the **central axis** (e.g., "longitudinal axis") of the impeller 74. I note that in parallel litigation, the Patent Owner has asserted that the blood outflow port of the "HeartMate 3" is "radially adjacent" to a magnetically driven rotor in the same way as described above in Wampler-169. *See* Ex.1019, at pp. 10-11 (Complaint, Ex. 13). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "discharge tube 16") is "radially adjacent" to the guide surfaces of the **rotor** (e.g., the "impeller 74") in the same way.

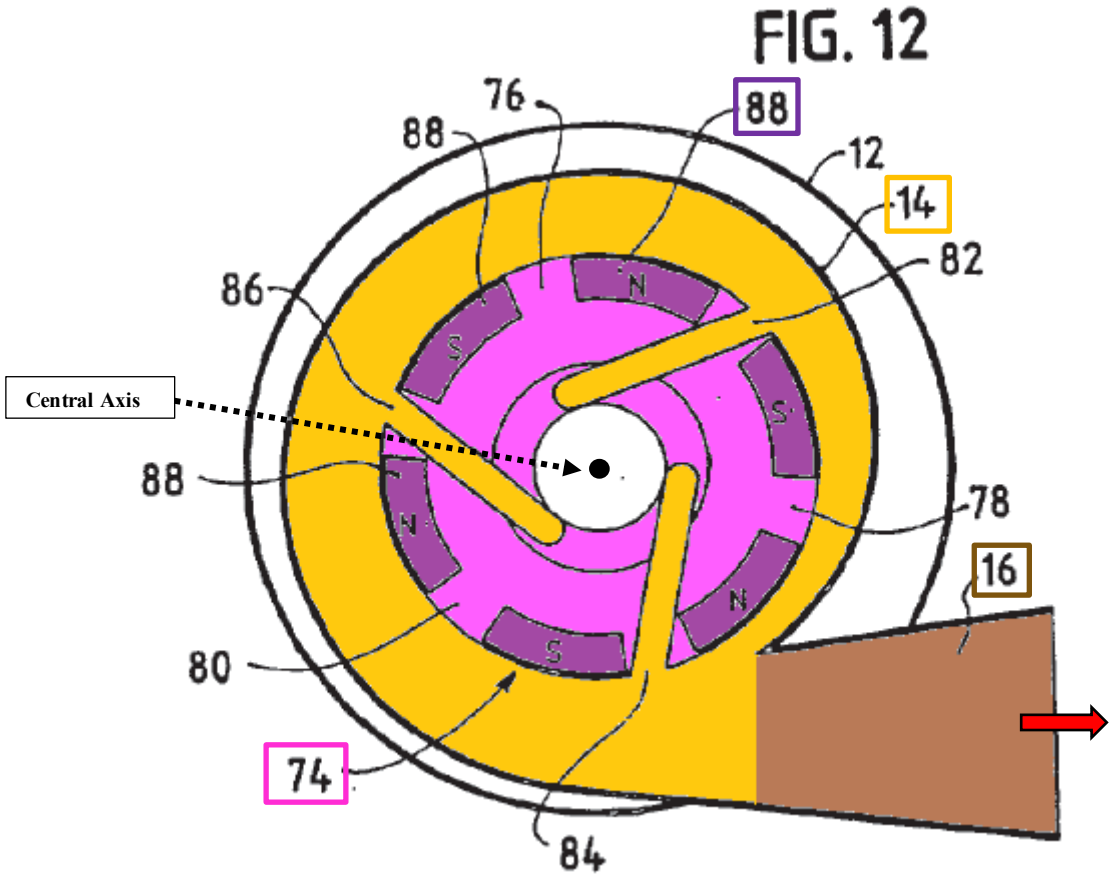
236. Figure 13 (annotated) illustrates a cross-sectional view of the pump 11 where the discharge tube 16 (**brown**) is radially adjacent to the impeller 74 of the rotor (**pink**) such that blood is driven (black arrows) by the impeller to exit the casing

14 (**orange**) in a direction substantially perpendicular from the inlet tube (**green**) and the central (or longitudinal) axis (**black**) of the impeller 74:



Ex.1008, Fig. 13 (annotated).

237. Similarly, Figure 12 (annotated) shows a top view of the pump 11 further illustrating that the discharge tube 16 (**brown**) is radially adjacent to the impeller 74 of the rotor (**pink**) having magnetic pieces 88 (**purple**) such that blood is driven (**red** arrow) by the impeller to exit the casing 14 (**orange**) in a direction substantially perpendicular from the inlet tube and the central (or longitudinal) axis (**black**) of the impeller 74:



Ex.1008, Fig. 6 (annotated).

238. Accordingly, Wampler-169 discloses "*a* ***blood outflow port*** ("discharge tube 16") *positioned radially adjacent the guide surfaces of the* ***rotor*** ("impeller 74") *such that, when blood is driven by the* ***magnetically driven rotor assembly,*** *the blood exits the* ***surrounding stationary housing*** ("casing 14") *in a direction substantially perpendicular to the* ***central axis*** *of the* ***magnetically driven rotor assembly***."

xii. [1K] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and

239. Wampler-169 discloses that "*the magneto coupling is configured to both drive rotation the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **surrounding stationary housing** by the gap sized for passage of the blood*."

240. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the gap sized for passage of the blood**" to mean that the "blood flowing" "in response to rotation of the magnetically driven rotor" ***causes*** the "magnetically driven rotor" to remain "entirely spaced apart from the surrounding rotor housing." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that my narrower interpretation of the plain and ordinary meaning of this phrase is correct. *See* Ex.1019. However, whether this limitation is interpreted broadly (to include *exclusively* magnetic

suspension) or narrowly (to require the blood flowing to cause suspension of the rotor), my narrower interpretation would in any event be included within the broader interpretation.

241. Accordingly, as discussed with respect to element [1G], Wampler-169 discloses a magneto coupling between the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller 74, Ex.1008, [0080]) to drive rotation of the **rotor** (e.g., "impeller 74").

242. In addition, as discussed with respect to element [1F], Wampler-169 discloses that in the embodiments described with respect to Figures 11-14, "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Referring to FIGS. 11 and 11*a* in particular, hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102 and 103 are illustrated." Ex.1008, [0089]. Note that these embodiments do not include the mechanical "thrust bearings" included in the embodiments, described with respect to Figures 1-8.

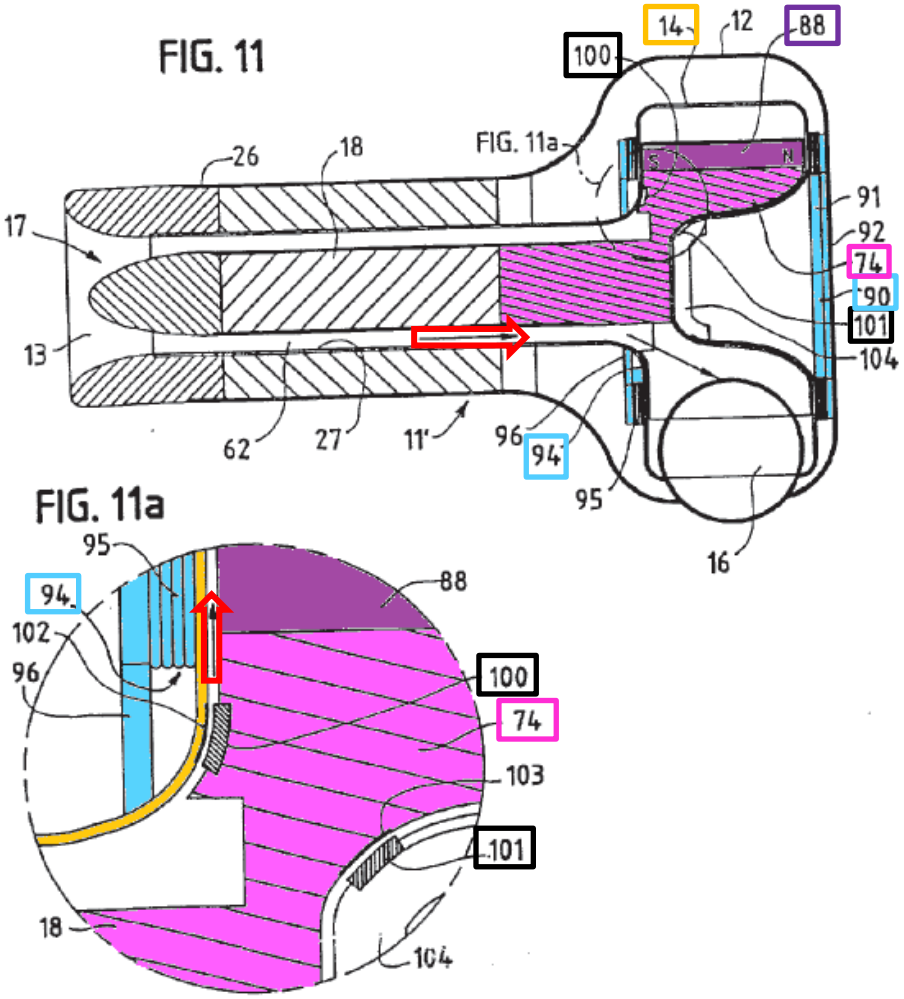
243. "The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the FIGS. 11 and 11 *a* embodiment, the raised pads 100

are carried by the impeller and the raised pads 101 are carried by a cup-shaped member 104 that is fastened to the casing." Ex.1008, [0091]. Such "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093].

244. In the embodiment described with respect to Figures 11-14, Wampler-169 teaches that "[t]he hydrodynamic bearings are formed by a raised pad ***spaced from a contact surface by the blood gap***. Although at rest there may be contact between the impeller and the casing, ***once rotation begins*** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap ***which forces the raised pad and the contact surface apart***." Ex.1008, [0092].

245. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the hydrodynamic bearings formed by raised pads 100 and 101 (**black**), which serve to increase pressure within the bearing gap such that, once rotation of the impeller 74 (**pink**), the blood flowing (**red** arrow)

forces the raised pad and the contact surface apart: begins magneto coupling between "magnetic pieces 88" (**purple**) of the impeller and the "motor stators 90 and 94" (**light blue**):



Ex.1008, Figs. 11 and 11*a* (annotated).

246. Thus, the "magneto coupling" between the "magnetic pieces 88" of the impeller 74 and the "motor stators 90 and 94" drives rotation of the impeller 74 and

in response to that rotation, the hydrodynamic bearing "forces the raised pad and the contact surface apart," such that the impeller 74 and magnetic pieces 88 remain entirely spaced apart from the casing 14 by the blood flowing from the inlet tube 13 to the discharge tube 16.

247. Thus, for the same reasons discussed with respect to elements [1C] and [1F] above, Wampler-169 discloses that the **magnetically driven rotor assembly** ("impeller 74") and **first magnetic device** ("magnetic pieces 88"), which are rigidly coupled, are entirely spaced apart from the **surrounding stationary housing** ("casing 14") by a gap (e.g., "once rotation begins each hydrodynamic bearing…forces the raised pad and the contact surface apart") during rotation of the **magnetically driven rotor assembly**.

248. Accordingly, Wampler-169 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly*** ("impeller 74" and "magnetic pieces 88") *and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **surrounding stationary housing*** ("casing 14") *by the gap sized for passage of the blood."*

xiii. [1L] an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,

249. Wampler-169 discloses "*an **external control unit** configured to regulate operation of the **second magnetic device** based upon a control value indicative of cardiac output.*"

250. With respect to the embodiments described in Figures 1-8, Wampler-169 discloses the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion. The back EMF resulting from the magnets 54 passing by the windings is detected by the controller. The controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor." Ex.1008, [0072]. The "motor stators 90 and 94" described with respect to the embodiments of Figures 11-14 would be energized by the controller 59 to produce an electromagnetic field in the same way. Ex.1008, [0085]. Wampler-169 states that the difference in the "dual stator design" is that this design would provide additional "radial restoring force" and "system redundancy." Ex.1008, [0087]-[0088].

251. According to the disclosure, "it is contemplated that controller 59 and power supply 61 may be worn externally by the user …" Ex.1008, [0070]. The "controller 59" described in Wampler-169 may "include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump." Ex.1008, [0072]. However, the controller 59 may also "have interactive and automatic capabilities," for example by being "interconnected to sensors on various organs of the user…" Ex.1008, [0072].

252. The "controller 59" described in Wampler-169 is an **external control unit** as recited in Claim 1 which regulates operation of the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** (e.g., "impeller 74" and "magnetic pieces 88" of the rotor, Ex.1008, [0081]) via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller, Ex.1008, [0080]).

253. Figure 5 (annotated) illustrates the connection of the controller 59 (**lime green**) to the pump 11 (**blue**):

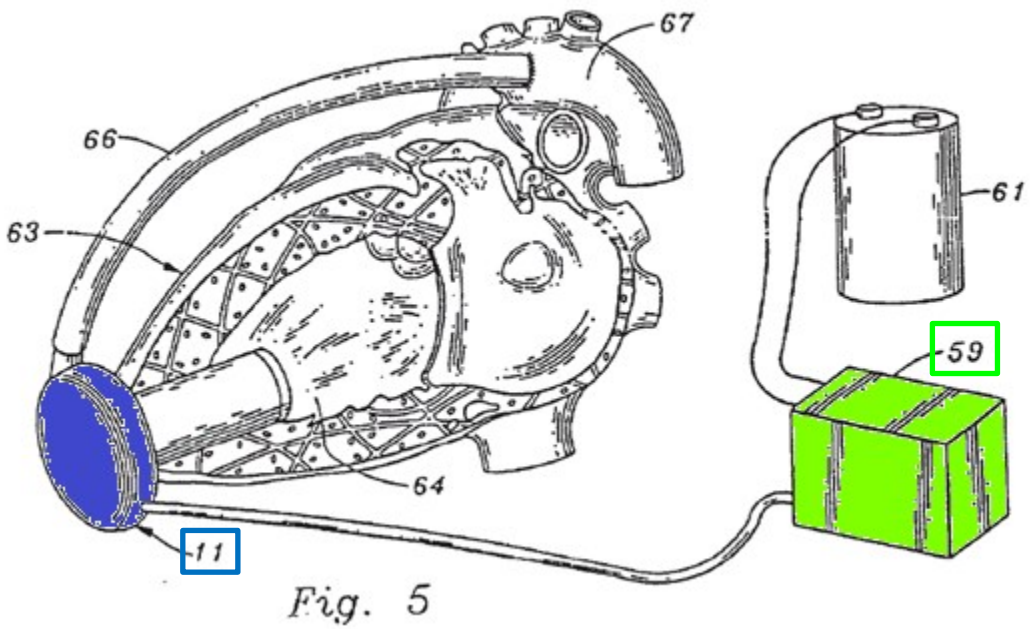


Fig. 5

Ex.1008, Fig. 5 (annotated).

254. As discussed above, the "controller 59" described in Wampler-169 is an **external control unit** as recited in Claim 1 which regulates operation of the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]).

255. The 077 Patent does not define "a control value indicative of cardiac output." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 external control unit is configured to control the operation of the second magnetic device using a control value, such as what Abbott calls a "fixed speed" or "lower speed limit" which is indicative of cardiac output (e.g. output as measured in liters of blood per minute.

See, e.g., Ex.1019, (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "a control value indicative of cardiac output."

256. Accordingly, Wampler-169 further discloses that the "control unit allows the speed and drive cycle of the motor either ***to be programmed*** or interactively determined by the user's physical activity or condition." Wampler-169, [0018], [0071] ("Controller 59 may include circuitry as simple as a variable voltage or current control, ***manually adjusted or programmed*** to determine the running rate of pump. However, controller 59 may also have interactive and automatic capabilities. For example, controller 59 may be interconnected to sensors on various organs of the user, automatically and instantaneously ***to tailor operation of the pump to the user's physical activity and condition***.").

257. Thus, the "controller 59" is an **external control unit** as recited in Claim 1 that controls the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) in response to measurement values indicative of cardiac output of the heart (e.g., "controller 59" may be "manually adjusted or programmed to determine the running rate of pump" in order "to tailor operation of the pump to the user's physical activity and condition" Ex.1008, [0071]).

258. Accordingly, Wampler-169 discloses "*an **external control unit*** ("controller 59") *configured to regulate operation of the **second magnetic device*** ("motor stators 90 and 94") *based upon a control value indicative of cardiac output*."

xiv. [1M] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,

259. Wampler-169 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device***."

260. As discussed with respect to element [1L], the "controller 59" described in Wampler-169 is an **external control unit** as recited in Claim 21 which regulates operation of the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]).

261. The "controller 59" described in Wampler-169 is also connectable to "blood pump 11" for controlling the "motor stators 90 and 94" to thereby magnetically drive the rotation of the "impeller 74" of the rotor via the magneto coupling with the "magnetic pieces 88" imbedded in the impeller.

262. Figure 5 (annotated) illustrates the connection of the controller 59 (**lime green**) to the pump 11 (**blue**):

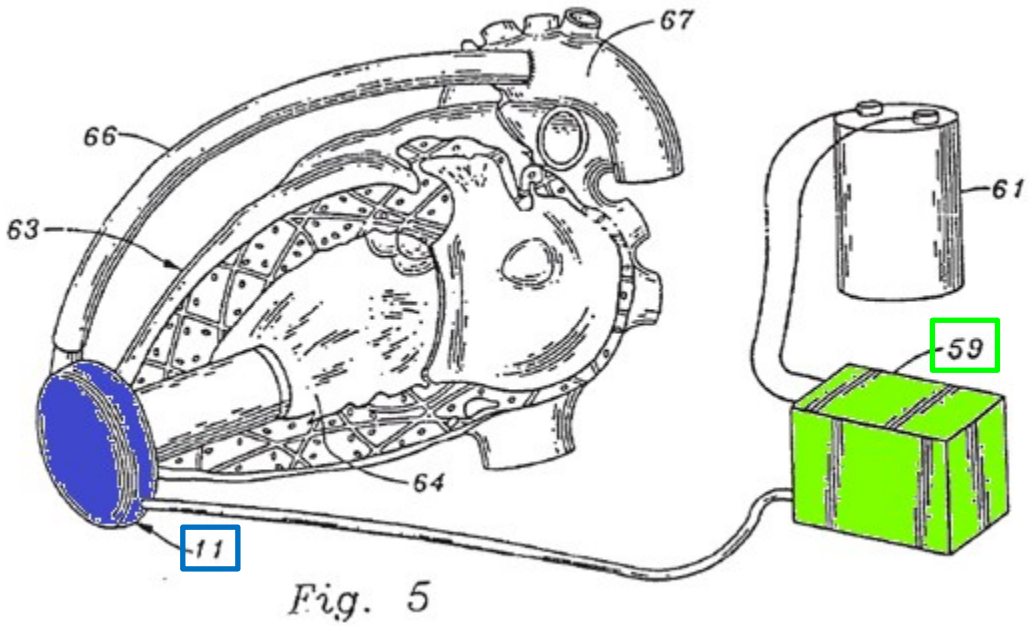


Fig. 5

Ex.1008, Fig. 5 (annotated).

263. The "controller 59" described in Wampler-169 is an **external control unit** as recited in Claim 1 which regulates operation of the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) to thereby magnetically drive the rotation of the **magnetically driven rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]) via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller, Ex.1008, [0080]).

264. Figure 5 (annotated) illustrates the connection of the controller 59 (**lime green**) to the pump 11 (**blue**):

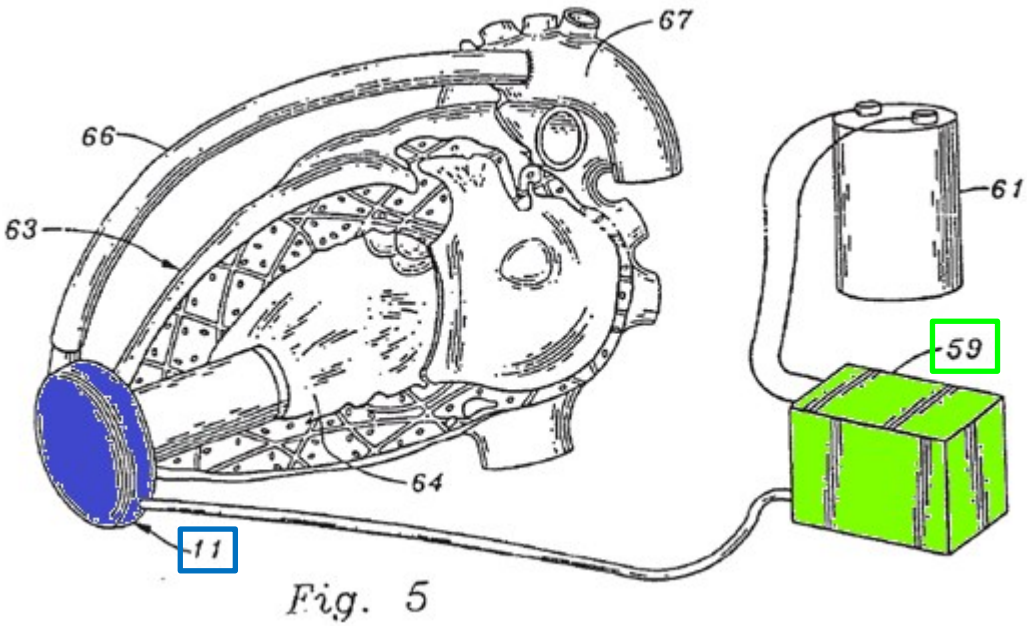


Fig. 5

Ex.1008, Fig. 5 (annotated).

265. Accordingly, Wampler-169 discloses that "*the **external control unit*** ("controller 59") *is connectable to the **heart assist pump device*** ("blood pump 11"") *for controlling the **second magnetic device*** ("motor stators 90 and 94") *to thereby magnetically drive the rotation of the **magnetically driven rotor assembly*** ("impeller 74") *via the magneto coupling with the **first magnetic device*** ("magnetic pieces 88")."

266. Based on my analysis, Wampler-169 discloses each and every element of Claim 1 of the 077 Patent.

2. Claims 2, 3, and 4

267. Claim 4 depends from dependent claim 3 which depends from dependent Claim 2 which depends from independent Claim 1. Accordingly, I address each dependent claim in turn.

a. [2] The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.

268. Wampler-169 discloses and/or renders obvious claim 2. I have already explained how Wampler-169 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 2.

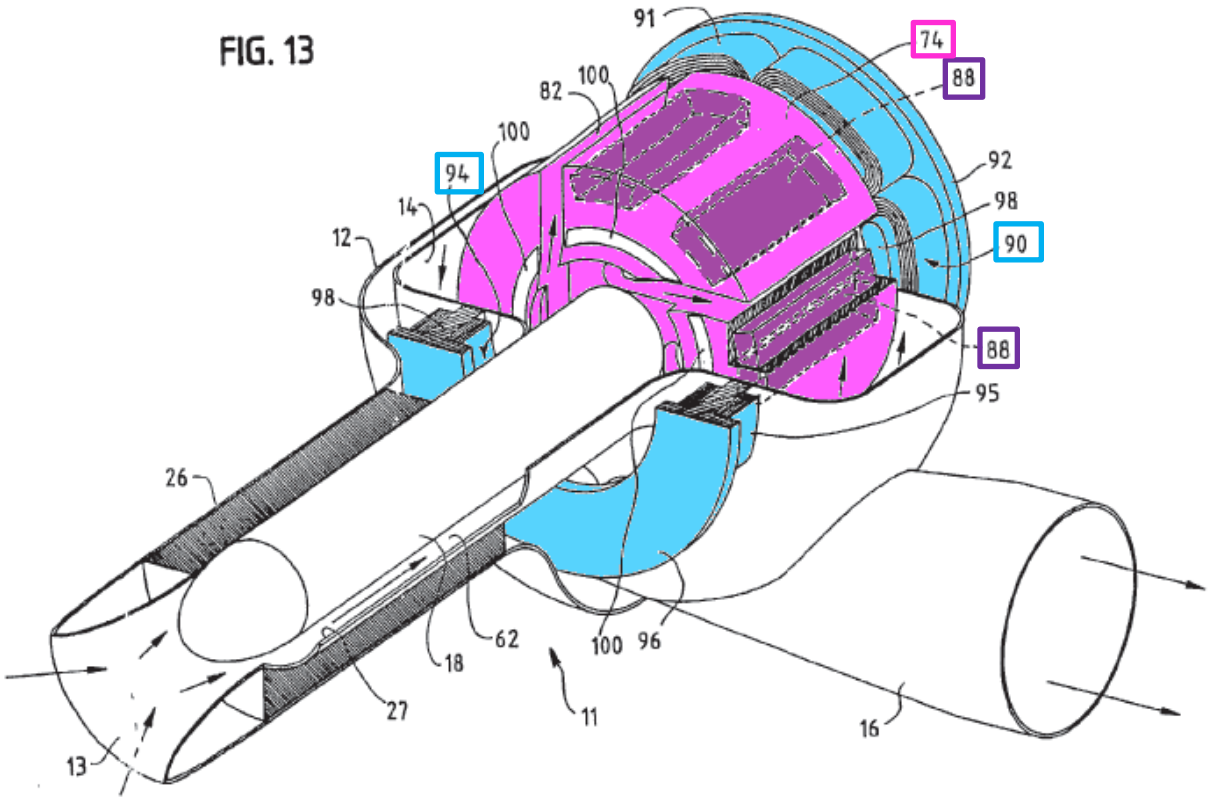
269. Wampler-169 discloses that "*the **first magnetic device** is configured to be positioned between the **second magnetic device** and the guide surfaces of the **rotor** of the **magnetically driven rotor assembly**.*"

270. As discussed with respect to element [1G], Wampler-169 discloses that the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is positioned to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0083]), via the magneto coupling with the **first magnetic device**

(e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]). *See supra* Section X.A.1.viii.

271. For example, with respect to the embodiments described in Figures 1-8, Wampler-169 discloses the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion. The back EMF resulting from the magnets 54 passing by the windings is detected by the controller. The controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor." Ex.1008, [0072]. The "motor stators 90 and 94" described with respect to the embodiments of Figures 11-14 would be energized by the controller 59 to produce an electromagnetic field in the same way. Ex.1008, [0085].

272. Thus, the "magnetic pieces 88" imbedded in the impeller 74 are necessarily between the "motor stators 90 and 94" and the "impeller 74" in order for the motor to drive the impeller's motion. Figure 13 (annotated) illustrates that the magnetic pieces 88 (**purple**) are positioned between the motor stators 90 and 94 (**light blue**) and the impeller 74 (**pink**) in order to drive rotation via the magneto coupling:



Ex.1008, Fig. 13 (annotated).

273. Accordingly, Wampler-169 discloses that "*the **first magnetic device*** ("magnetic pieces 88") *is configured to be positioned between the **second magnetic device*** ("motor stators 90 and 94") *and the guide surfaces of the **rotor*** ("impeller 74") *of the **magnetically driven rotor assembly***."

b. [3] The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.

274. Wampler-169 discloses claim 3. I have already explained how Wampler-169 discloses each and every element of claims 1 and 2. I incorporate that discussion into my analysis for claim 3.

275. Wampler-169 discloses that "*the **first magnetic device** is configured to rotate together with the **rotor** relative to the **surrounding stationary housing***."

276. As discussed with respect to element [1C], the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]) is rigidly coupled to the **magnetically driven rotor** (e.g., "impeller 74"). *See supra* Section X.A.1.iv. And as discussed with respect to element [1G], Wampler-169 discloses the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is positioned to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]), via the magneto coupling with the **first magnetic device** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]). *See also* Ex.1008, [0074] ("Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62."), [0018] ("Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent

magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing."), [0085].

277. In addition, Wampler-169 discloses that "[a]lthough at rest there may be contact between the impeller and the casing, once rotation begins each hydrodynamic bearing is structured so that ***during relative movement between the raised pad and the contact surface*** the hydrodynamic action of the fluid film produces increased pressure within the bearing gap which forces the raised pad and the contact surface apart." Ex.1008, [0092].

278. For the same reasons, because the "magnetic pieces 88" are rigidly coupled (or "imbedded") to the "impeller 74," the "magnetic pieces 88" rotate together with the "impeller 74" relative to and within the casing 14.

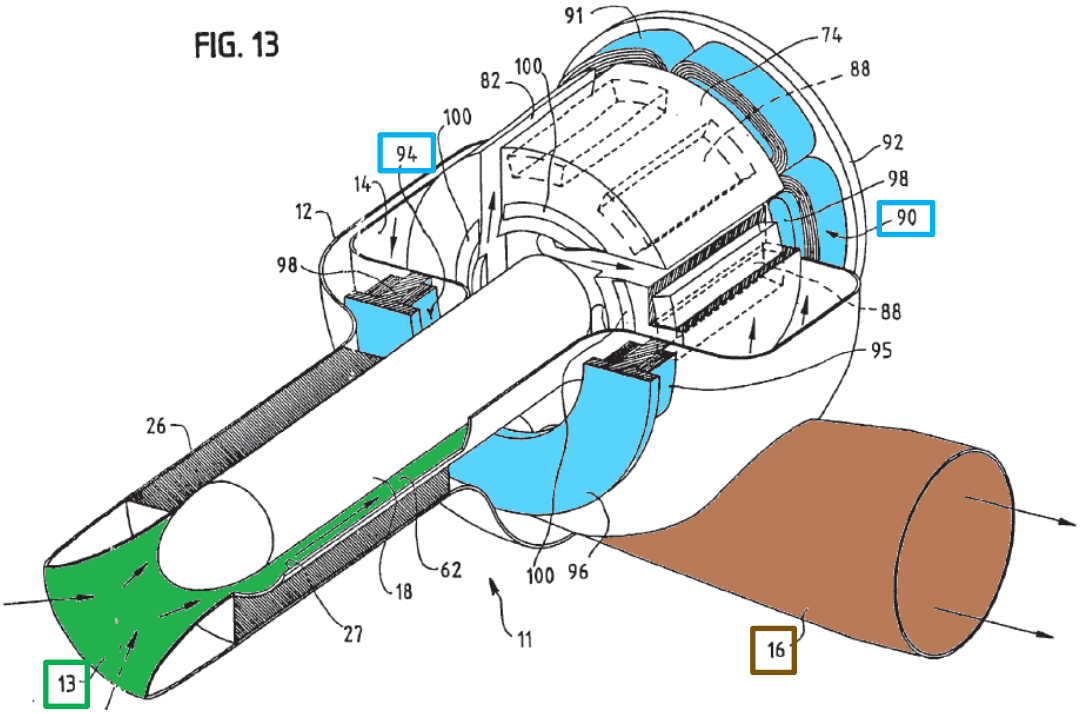
279. Accordingly, Wampler-169 discloses that "*the **first magnetic device*** ("magnetic pieces 88") *is configured to rotate together with the **rotor*** ("impeller 74") *relative to the **surrounding stationary housing*** ("casing 14")."

c. [4] The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.

280. Wampler-169 discloses claim 4. I have already explained how Wampler-169 discloses each and every element of claims 1, 2 and 3. I incorporate that discussion into my analysis for claim 4.

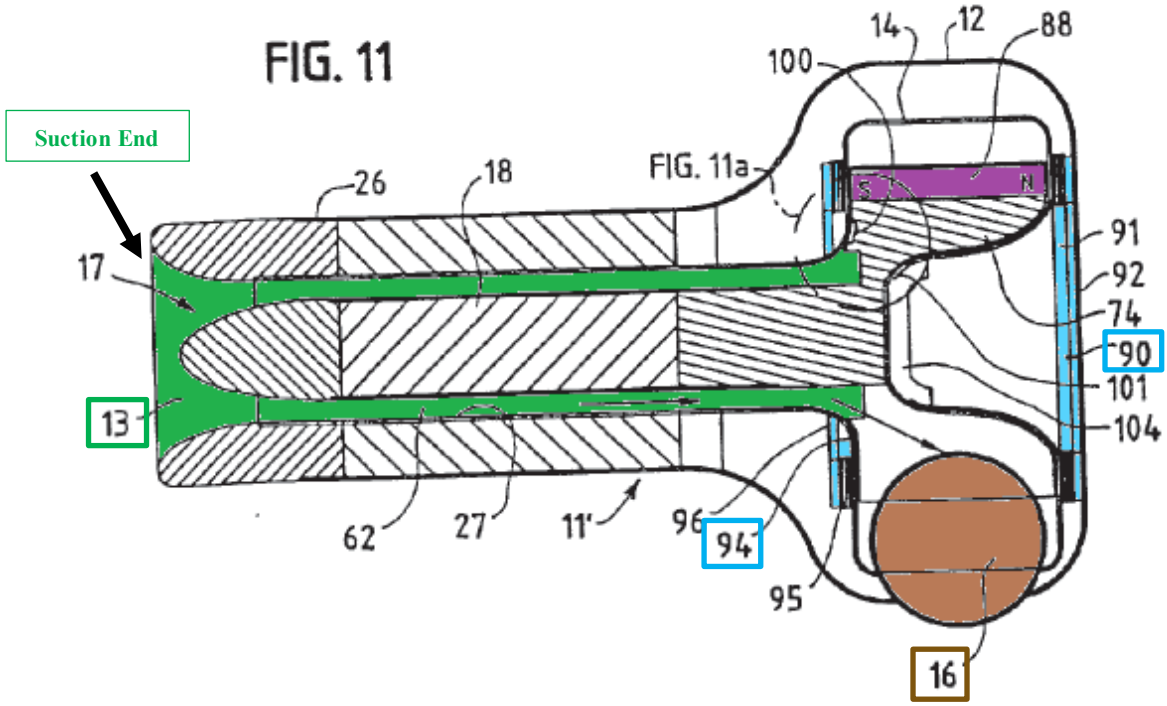
281. Wampler-169 discloses that "*the **second magnetic device** is positioned closer to the **blood outflow port** than to the suction end of the **inflow tube**.*"

282. For example, Figure 13 (annotated) illustrates that the "motor stators 90 and 94" (**light blue**) are positioned closer to the discharge tube 16 (**brown**) than the "motor stators 90 and 94" are positioned relative to the suction end of the inlet tube 13 (**green**):



Ex.1008, Fig. 13 (annotated).

283. Figure 11 (annotated) illustrates the same:



Ex.1008, Fig 11 (annotated).

284. Accordingly, Wampler-169 discloses that "*the second magnetic device* ("motor stators 90 and 94") *is positioned closer to the blood outflow port* ("discharge tube 16") *than to the suction end of the inflow tube* ("inlet tube 13")."

3. Claim 5

a. [5] The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.

285. Wampler-169 discloses claim 5. I have already explained how Wampler-169 discloses each and every element of claim 1. I incorporate that discussion into my analysis for claim 5.

286. Wampler-169 discloses that "*the **magnetically driven rotor assembly** is sealed from the **second magnetic device** and a drive source configured to regulate the operation of the **second magnetic device**.*"

287. As discussed with respect to [1H], the **impeller 74** and **magnetic pieces 88** are sealed from **motor stators 90 and 94**.

288. Further, as discussed with respect to elements [1L] and [1M], Akamatsu-1999 discloses a "controller" that exists outside the heart and which is a drive source that provides "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump. Ex.1006 at 3, 4. *See supra* Section X.C.1.xiii.

289. Accordingly, Wampler-169 discloses that "*the **magnetically driven rotor assembly*** ("impeller 74" and "magnetic pieces 88") *is sealed from the **second***

magnetic device ("motor stators 90 and 94") *and a drive source configured to regulate the operation of the* ***second magnetic device***."

4. Claim 7

a. [7] The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

290. Wampler-169 discloses claim 7. I have already explained how Wampler-169 discloses each and every element of claim 1. I incorporate that discussion into my analysis for claim 7.

291. Wampler-169 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit***."

292. For example, Wampler-169 discloses "[t]he controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor." Ex.1008, [0072]. The "controller 59" described in Wampler-169 may "include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump." Ex.1008, [0072]. However, the controller 59 may also "have interactive and automatic capabilities," for example by being "***interconnected to sensors on various organs of the user***, automatically and instantaneously to tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0071], [0072], [0018] ("The

control unit allows the speed and drive cycle of the motor either to be programmed or interactively determined by the user's physical activity or condition."). Thus, the **external control unit** (e.g., **"**controller 59") may have "interactive and automatic capabilities," such as for receiving feedback signals from "sensors" to "tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0071]. [0072].

293. Accordingly, Wampler-169 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit*** ("controller 59")."

5. Claim 10

a. [10] The system of claim 1, wherein the heart assist pump device is a catheter device.

294. Wampler-169 discloses claim 10. I have already explained how Wampler-169 discloses each and every element of claim 1. I incorporate that discussion into my analysis for claim 10.

295. Wampler-169 discloses that "*the* ***heart assist pump device*** *is a catheter device*."

296. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See, e.g.*,

Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "catheter device."

297. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], the pump 11 disclosed in Wampler-169 includes a "catheter" which is an **inflow tube** (e.g., "inlet tube 13," Ex.1008, [0080]) that "serves as the inflow cannula and is placed into the apex of the left ventricle 64." Ex.1008, [0075]. Therefore, the centrifugal pump disclosed in Wampler-169 is a catheter device.

298. Accordingly, Wampler-169 discloses that "*the **heart assist pump device*** ("blood pump 11"") *is a catheter device*."

6. Claim 16

299. As demonstrated below, the scope of claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. For instance, the "surrounding stationary housing" of claim 1 is essentially the same as the "chamber walls at least partially defining a chamber" of claim 16. Similarly, because the "inflow tube" and "central axis" of claim 1 are aligned, the claimed "inflow axis" of claim 16 is rendered obvious for the same reasons.

a. [16pre] A system for assisting blood circulation of a heart, the system comprising

300. Wampler-169 discloses "*a system for assisting blood circulation of a* ***heart***."

301. This element is invalid for the same reasons discussed above in [1PRE], thus, I incorporate that discussion into my analysis here.

302. Accordingly, Wampler-169 discloses "*a system for assisting blood circulation of a* ***heart***."

b. [16a] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;

303. Wampler-169 discloses "*a* ***heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** *along an* ***inflow axis*** *and being insertable into* ***a left ventricle***."

304. This element is invalid for the same reasons discussed above in [1A] and [1B], thus, I incorporate that discussion into my analysis here.

305. Accordingly, Wampler-169 discloses "*a* ***heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** *along an* ***inflow axis*** *and being insertable into* ***a left ventricle***."

c. [16b] chamber walls at least partially defining a chamber to receive blood from the inflow tube;

306. Wampler-169 discloses "***chamber walls at least partially defining a chamber*** *to receive blood from the* ***inflow tube***."

307. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here. For example, Wampler-169 discloses "***walls…defining a chamber***" of [16B] for the reasons it discloses a "***surrounding stationary housing***" of [1E].

308. Accordingly, Wampler-169 discloses "***chamber walls at least partially defining a chamber*** *to receive blood from the* ***inflow tube***."

d. [16c] a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device

309. Wampler-169 discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

310. This element is invalid for the same reasons discussed above in [1B] and [1C], thus, I incorporate that discussion into my analysis here.

311. Accordingly, Wampler-169 discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

e. [16d] that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor

312. Wampler-169 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

313. This element is invalid for the same reasons discussed above in [1C], thus, I incorporate that discussion into my analysis here.

314. Accordingly, Wampler-169 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

f. [16e] [the rotor] having guide surfaces to produce centrifugal flow components,

315. Wampler-169 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

316. This element is invalid for the same reasons discussed above in [1D], thus, I incorporate that discussion into my analysis here.

317. Accordingly, Wampler-169 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

g. [16f] the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation

318. Wampler-169 discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

319. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

320. Accordingly, Wampler-169 discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

h. [16g] [the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;

321. Wampler-169 discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

322. This element is invalid for the same reasons discussed above in [1B] and [1E], thus, I incorporate that discussion into my analysis here.

323. Accordingly, Wampler-169 discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

i. [16h] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

324. Wampler-169 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

325. This element is invalid for the same reasons discussed above in [1G], thus, I incorporate that discussion into my analysis here. For example, Wampler-169 discloses a "***magnetic drive system comprising a second magnetic device***" of [16H] for the reasons it discloses a "***second magnetic device***" ("motor stators 90 and 94") of [1G]. Additionally, Wampler-169 discloses a "pump drive system ('*magnetic drive system*')" where "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing." Ex.1008, [0018].

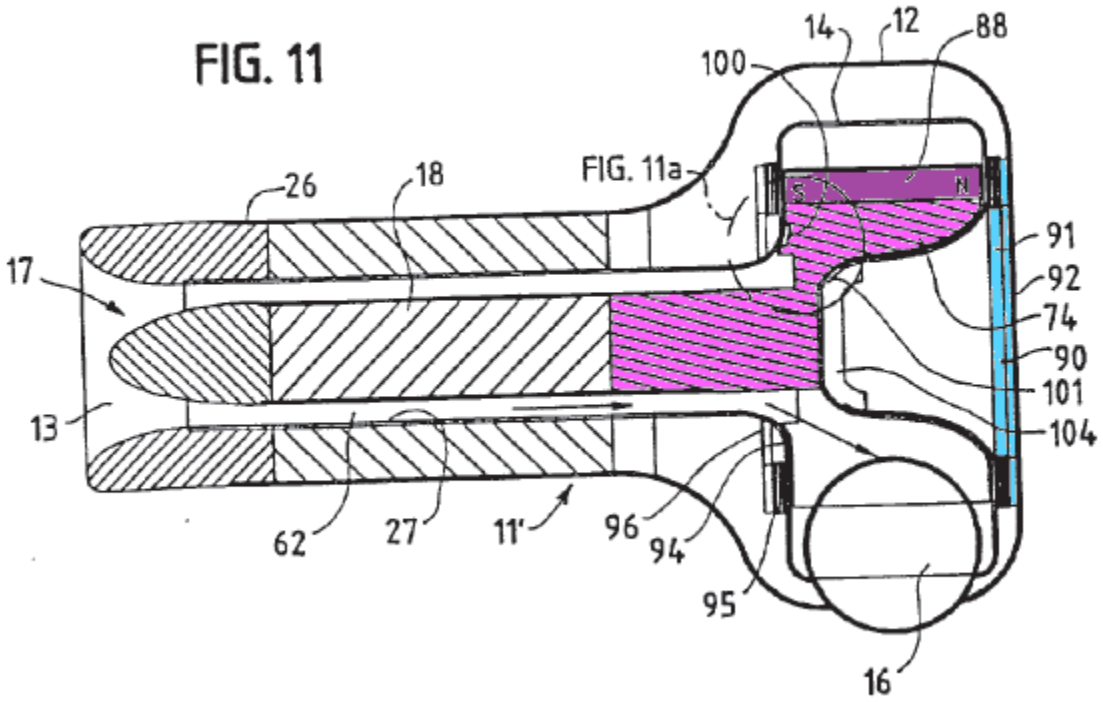
326. Accordingly, Wampler-169 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

j. [16i] the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and

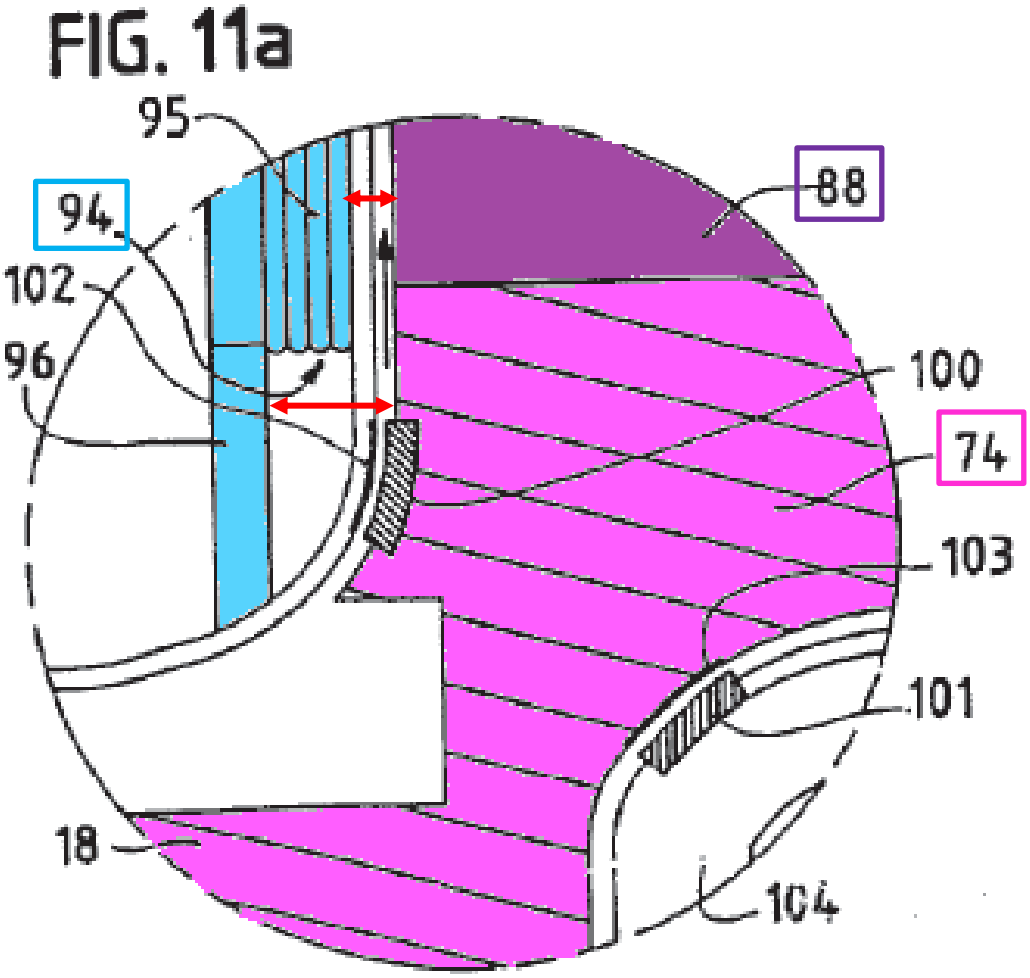
327. Wampler-169 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device***."

328. This element is invalid for the same reasons discussed above in [1B] and [1K] and [2], thus, I incorporate that discussion into my analysis here. Figure 11a (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) being "*axially closer*" to the "magnetic pieces 88" (**purple**) than the "impeller 74" (**pink**). To be "axially closer," components are configured such that they are colinear, or in the same line (or "axis") in space, and the ***second magnetic device*** is closer to the ***first magnetic device*** along that axis than it is to the ***magnetically driven rotor***. Wampler-169 thus discloses "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets [88]." Ex. 1008, [0085].

As shown in Figure 11 of Wampler-169, the **second magnetic device** (e.g., "motor stator[] 90") is positioned *axially closer* to the **first magnetic device** (e.g., "magnetic pieces 88") than to the **magnetically driven rotor** ("impeller 74"):



Ex.1008, [0085]. Additionally, Figure 11*a* of Wampler-169 illustrates that **motor stator 94**, which includes the "windings 95," is *positioned axially closer*" to the "**magnetic pieces 88**" than the "back iron 96" of the "**motor stators 90 and 94**" is to the "**impeller 74**" (shown by the lengths of the **red** arrows):



Ex.1008, Figs 11-11a. Indeed, the "windings" of the **motor stators 90 and 94**" must be positioned directly "adjacent" and therefore *axially closer* to the **magnetic pieces 88** for the "produce[d] an electromagnetic field" to be "effective to drive magnets 88" and thereby drive rotation of the **impeller 74**. Ex.1008, [0072], [0085]. To the extent that there is some portion of the **impeller 74** that is adjacent the "windings" of **motors stators 90 and 94**, the vast majority of the **impeller 74** is spaced

significantly farther apart from the **stators** than the **magnetic pieces 88** are positioned form the **stators**. In any event, it would have been obvious to position the **motor stators 90 and 94** "axially closer" to the **magnetic pieces 88** than to the **impeller**, because a POSITA would have been motivated to do so because the **motor stators** act upon the **magnetic pieces**— positioning those elements closer to each other would facilitate that action. Indeed, it is the "magnetic interaction" ['*magneto coupling*'] between the **permanent magnetic segments [88]** and the **circular electromagnetic stator [90 and 94]** that drives rotation of the **impeller**. Ex.1008, [0072], [0018].

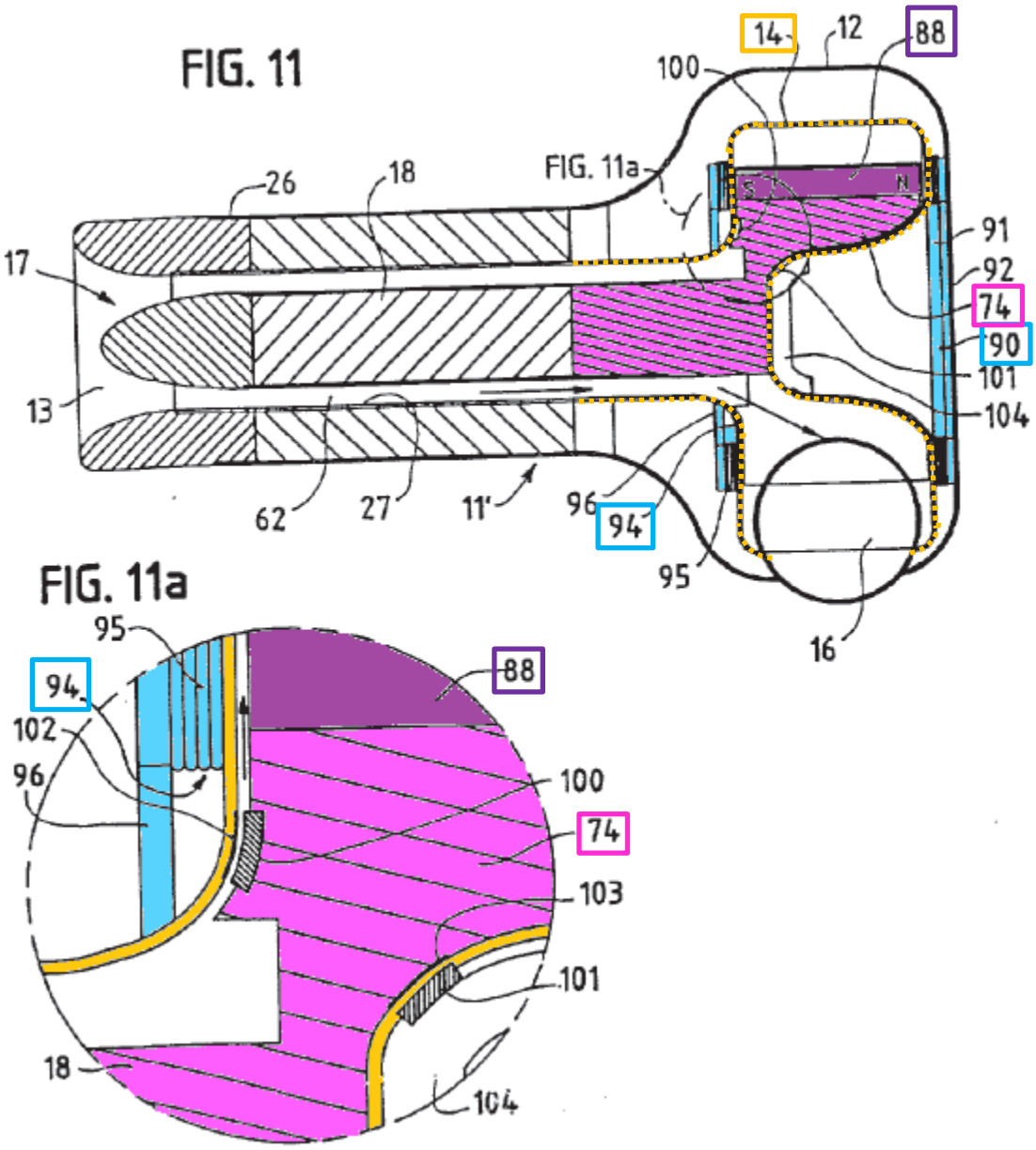
329. Accordingly, Wampler-169 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device**.*"

k. [16j] and [the second magnetic device is] spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,

330. Wampler-169 discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the***

chamber walls defining the chamber *is positioned between the* ***magnetically driven rotor assembly*** *and the* ***second magnetic device***."

331. This element is invalid for the same reasons discussed above in [1H], thus, I incorporate that discussion into my analysis here. Further, Wampler-169 discloses that a "***wall of the…chamber*** *is positioned between the* ***magnetically driven rotor assembly*** *and the* ***second magnetic device***" of [16J] for the reasons it discloses a "***second magnetic device***" is "*sealed*." Figures 11-11*a* illustrate the "**stator[s]** fixed between housing 12 and **casing 14**" while the "**impeller**" and its "**magnetic pieces 88**" are within the **casing**:



Ex.1008, Figs. 11-11*a*; Figs. 7-8*b*, [0070].

332. Accordingly, Wampler-169 discloses that the **second magnetic device** is "*spaced apart from the* ***magnetically driven rotor assembly*** *such that* ***a***

wall of the chamber walls defining the chamber *is positioned between the* ***magnetically driven rotor assembly*** *and the* ***second magnetic device***."

l. [16k] a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,

333. Wampler-169 discloses "*a* ***blood outflow port*** *positioned radially outward of the guide surfaces of the* ***rotor*** *such that, when the blood is driven by the* ***magnetically driven rotor assembly****, the blood exits the* ***chamber*** *in a direction substantially perpendicular to the* ***inflow axis***."

334. This element is invalid for the same reasons discussed above in [1J], thus, I incorporate that discussion into my analysis here.

335. Accordingly, Wampler-169 discloses "*a* ***blood outflow port*** *positioned radially outward of the guide surfaces of the* ***rotor*** *such that, when the blood is driven by the* ***magnetically driven rotor assembly****, the blood exits the* ***chamber*** *in a direction substantially perpendicular to the* ***inflow axis***."

m. [16l] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and

336. Wampler-169 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

337. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

338. Accordingly, Wampler-169 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

n. [16m] an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output

339. Wampler-169 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

340. This element is invalid for the same reasons discussed above in [1L], thus, I incorporate that discussion into my analysis here.

341. Accordingly, Wampler-169 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

o. [16n] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

342. Wampler-169 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device***."

343. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

344. Accordingly, Wampler-169 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

7. Claim 17

a. [17] The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.

345. Wampler-169 discloses claim 17. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 17.

346. Wampler-169 discloses that "*the **first magnetic device** is rigidly coupled to the **rotor** of the **magnetically driven rotor assembly** at a position between the **second magnetic device** and the **rotor**.*"

347. This element is invalid for the same reasons discussed above in [2], [16D], and [16I] above, thus, I incorporate that discussion into my analysis here.

348. Accordingly, Wampler-169 discloses that "*the **first magnetic device*** ("magnetic pieces 88") *is rigidly coupled to the **rotor*** ("impeller 74) *of the **magnetically driven rotor assembly** at a position between the **second magnetic device*** ("motor stators 90 and 94") *and the **rotor**.*"

8. Claims 18, 19, 20, and 21

349. Claims 18-21 are invalid for similar reasons.

a. [18] The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.

350. Wampler-169 discloses claim 18. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 18.

351. Wampler-169 discloses that the "*gap sized for passage of the blood is configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor assembly***."

352. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "**gap sized for passage of the blood** is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly" to mean that the "blood flowing" "when the second magnetic device drives rotation of the magnetically driven rotor" ***causes*** the "gap sized for passage of the blood." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that my narrower interpretation of the plain and ordinary meaning of this phrase is correct.

See Ex.1019. However, whether this limitation is interpreted broadly (to include *exclusively* magnetic suspension) or narrowly (to require the blood flowing to cause suspension of the rotor), my narrower interpretation would in any event be included within the broader interpretation.

353. Accordingly, as discussed with respect to element [1J], Wampler-169 discloses a magneto coupling between the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller 74, Ex.1008, [0080]) to drive rotation of the **magnetically driven rotor** (e.g., "impeller 74"). *See element* [1J].

354. In addition, Wampler-169 discloses that in the embodiments described with respect to Figures 11-14, "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Referring to FIGS. 11 and 11*a* in particular, hydrodynamic bearings in the form of raised pads 100, 101 and contact surfaces 102 and 103 are illustrated." Ex.1008, [0089]. Note that these embodiments do not include the mechanical "thrust bearings" included in the embodiments, described with respect to Figures 1-8.

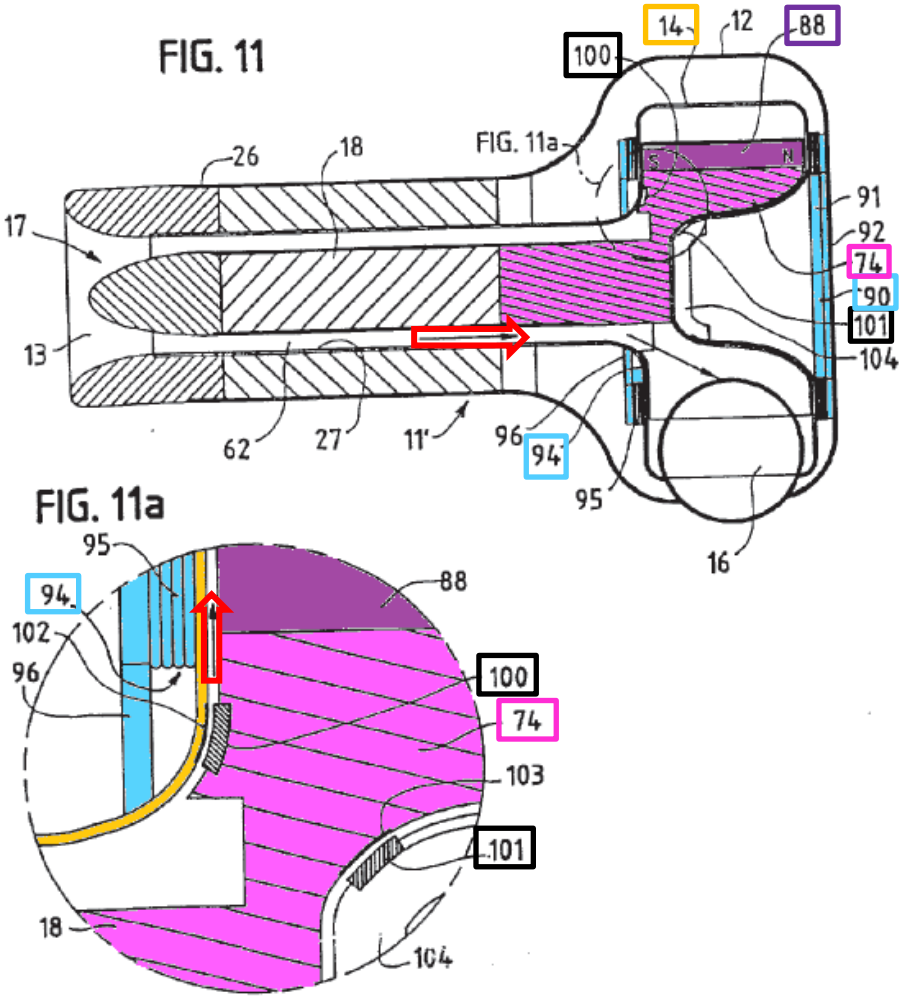
355. "The raised pads are carried by either the impeller or the casing, or an attachment to the casing. In the FIGS. 11 and 11 *a* embodiment, the raised pads 100

are carried by the impeller and the raised pads 101 are carried by a cup-shaped member 104 that is fastened to the casing." Ex.1008, [0091]. Such "hydrodynamic bearings can be located on the surface of the impeller to constrain axial motion and to provide radial support in the case of eccentric motion or shock on the device." Ex.1008, [0089]. "Depending upon the location of the hydrodynamic bearings, they can aid in axial support, radial support or both axial and radial support." Ex.1008, [0093].

356. In the embodiment described with respect to Figures 11-14, Wampler-169 teaches that "[t]he hydrodynamic bearings are formed by a raised pad ***spaced from a contact surface by the blood gap***. Although at rest there may be contact between the impeller and the casing, ***once rotation begins*** each hydrodynamic bearing is structured so that during relative movement between the raised pad and the contact surface the hydrodynamic action of the fluid film produces increased pressure within the bearing gap ***which forces the raised pad and the contact surface apart***." Ex.1008, [0092].

357. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the hydrodynamic bearings formed by raised pads 100 and 101 (**black**), which serve to increase pressure within the bearing gap such that, once rotation of the impeller 74 (**pink**), the blood flowing (**red** arrow)

forces the raised pad and the contact surface apart: begins magneto coupling between "magnetic pieces 88" (**purple**) of the impeller and the "motor stators 90 and 94" (**light blue**):



Ex.1008, Figs. 11 and 11*a* (annotated).

358. Thus, the "magneto coupling" between the "magnetic pieces 88" of the impeller 74 and the "motor stators 90 and 94" drives rotation of the impeller 74 and

in response to that rotation, the hydrodynamic bearing "forces the raised pad and the contact surface apart," such that the impeller 74 remains entirely spaced apart from the casing 14 by the blood flowing from the inlet tube 13 to the discharge tube 16.

359. As discussed with respect to element [1C], Wampler-169 discloses the "magnetic pieces 88" are a **first magnetic device** which is rigidly coupled to the **magnetically driven rotor assembly** because they are "imbedded" in the blade sectors 49 of the impeller 74." *See supra* Section X.A.1.iv. In addition, as discussed above, Wampler-169 discloses that in response to the rotation of the **magnetically driven rotor assembly** ("impeller 74"), the hydrodynamic bearing "forces the raised pad and the contact surface apart," such that the impeller 74 remains entirely spaced apart from the **surrounding stationary housing** ("casing 14") by the blood flowing from the inlet tube 13 to the discharge tube 16.

360. Thus, for the same reasons discussed with respect to element [1C] and above, Wampler-169 discloses that the gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the **magnetically driven rotor assembly** ("impeller 74").

361. Accordingly, Wampler-169 discloses that the "*gap sized for passage of the blood is configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor assembly*** ("impeller 74")*."*

b. [19] The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.

362. Wampler-169 discloses claim 19. I have already explained how Wampler-169 discloses each and every element of claim 18. I incorporate that discussion into my analysis for claim 19.

363. Wampler-169 discloses that "*the gap surrounds the* ***magnetically driven rotor assembly***."

364. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the* ***magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

365. Accordingly, Wampler-169 discloses that "*the gap surrounds the* ***magnetically driven rotor assembly***."

c. [20] The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.

366. Wampler-169 discloses claim 20. I have already explained how Wampler-169 discloses each and every element of claims 18 and 19. I incorporate that discussion into my analysis for claim 20.

367. Wampler-169 discloses that "*at least part of the gap extends radially outward from the* ***magnetically driven rotor assembly***."

368. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

369. Accordingly, Wampler-169 discloses that "*at least part of the gap extends radially outward from the **magnetically driven rotor assembly***."

d. [21] The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.

370. Wampler-169 discloses claim 21. I have already explained how Wampler-169 discloses each and every element of claims 18, 19, and 20. I incorporate that discussion into my analysis for claim 21.

371. Wampler-169 discloses that "*at least part of the gap extends along a face of the **magnetically driven rotor assembly** that is axially opposite from the **inflow tube***."

372. The 077 patent does not define "*along a face*," thus, I interpret the term "face" to mean the surface of the rotor on the side opposite the inflow port, which may include curved and flat portions. Therefore, this element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends

entirely surrounding *the* ***magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

373. Accordingly, Wampler-169 discloses that "*at least part of the gap extends along a face of the* ***magnetically driven rotor assembly*** *that is axially opposite from the* ***inflow tube***."

9. Claims 22 and 23

374. Claim 23 depends from dependent Claim 22. Accordingly, I address this dependent claim herein.

a. [22] The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

375. Wampler-169 discloses claim 22. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 22.

376. Wampler-169 discloses that "*the* ***chamber*** *is a first chamber within which the* ***magnetically driven rotor assembly*** *is positioned, and the magnetic drive system is positioned within a* ***second chamber*** *sealed from the* ***first chamber***."

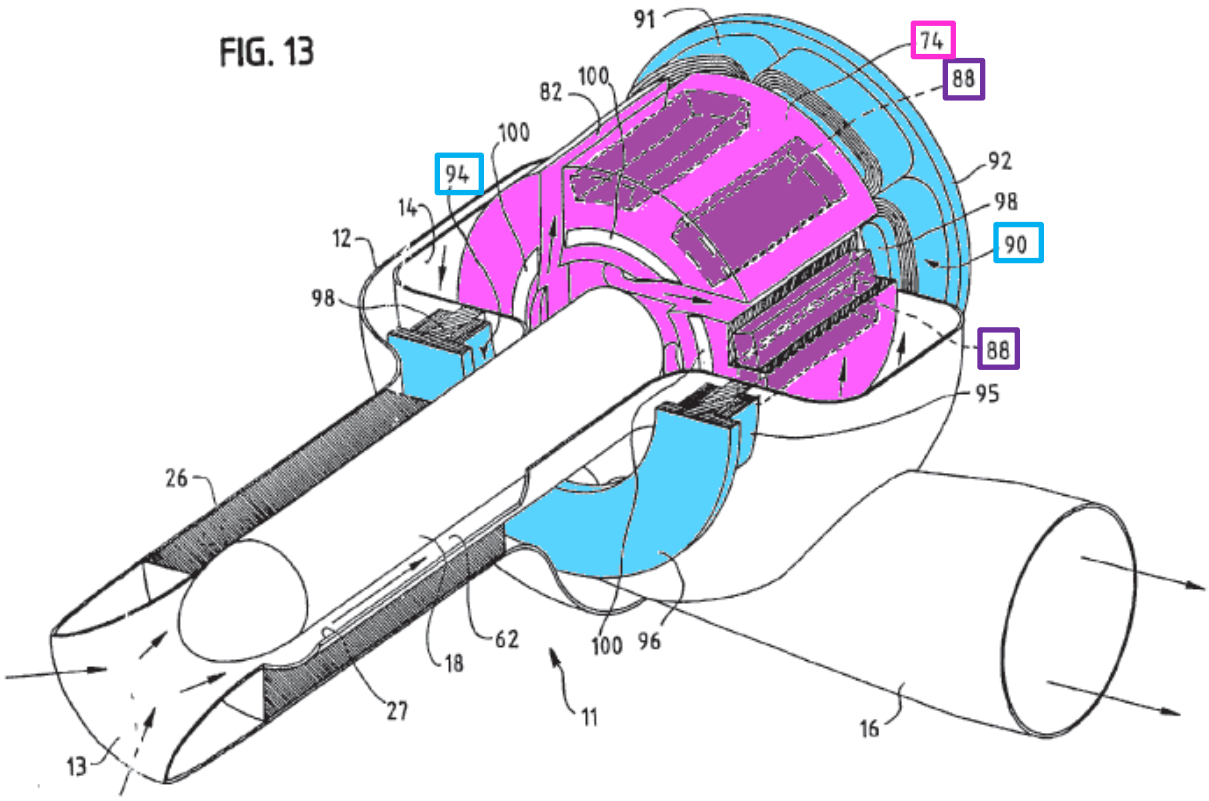
377. As discussed with respect to element [1G], Wampler-169 discloses that the **second chamber** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is positioned

to drive rotation of the **magnetically driven rotor assembly** (e.g., "impeller 74" of the rotor, Ex.1008, [0083]), via the magneto coupling with the **first chamber** (e.g., the "magnetic pieces 88" of the impeller, Ex.1008, [0080]). *See supra* Section X.A.1.viii.

378. For example, with respect to the embodiments described in Figures 1-8, Wampler-169 discloses the "windings 57" of the motor stator 56 "are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17, in a rotary fashion. The back EMF resulting from the magnets 54 passing by the windings is detected by the controller. The controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor." Ex.1008, [0072]. The "motor stators 90 and 94" described with respect to the embodiments of Figures 11-14 would be energized by the controller 59 to produce an electromagnetic field in the same way. Ex.1008, [0085].

379. Thus, the "magnetic pieces 88" imbedded in the impeller 74 are necessarily between the "motor stators 90 and 94" and the "impeller 74" in order for the motor to drive the impeller's motion. Figure 13 (annotated) illustrates that the magnetic pieces 88 (**purple**) are positioned between the motor stators 90 and 94

(**light blue**) and the impeller 74 (**pink**) in order to drive rotation via the magneto coupling:



Ex.1008, Fig. 13 (annotated).

380. As discussed with respect to element [1E], Wampler-169 discloses that the "rotary blood pump includes a housing and a pump rotor," where the housing "includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller." Ex.1008, [0012]; *see also* [0081] ("Pump rotor 17 is located within housing 12, ***within casing 14***, and includes

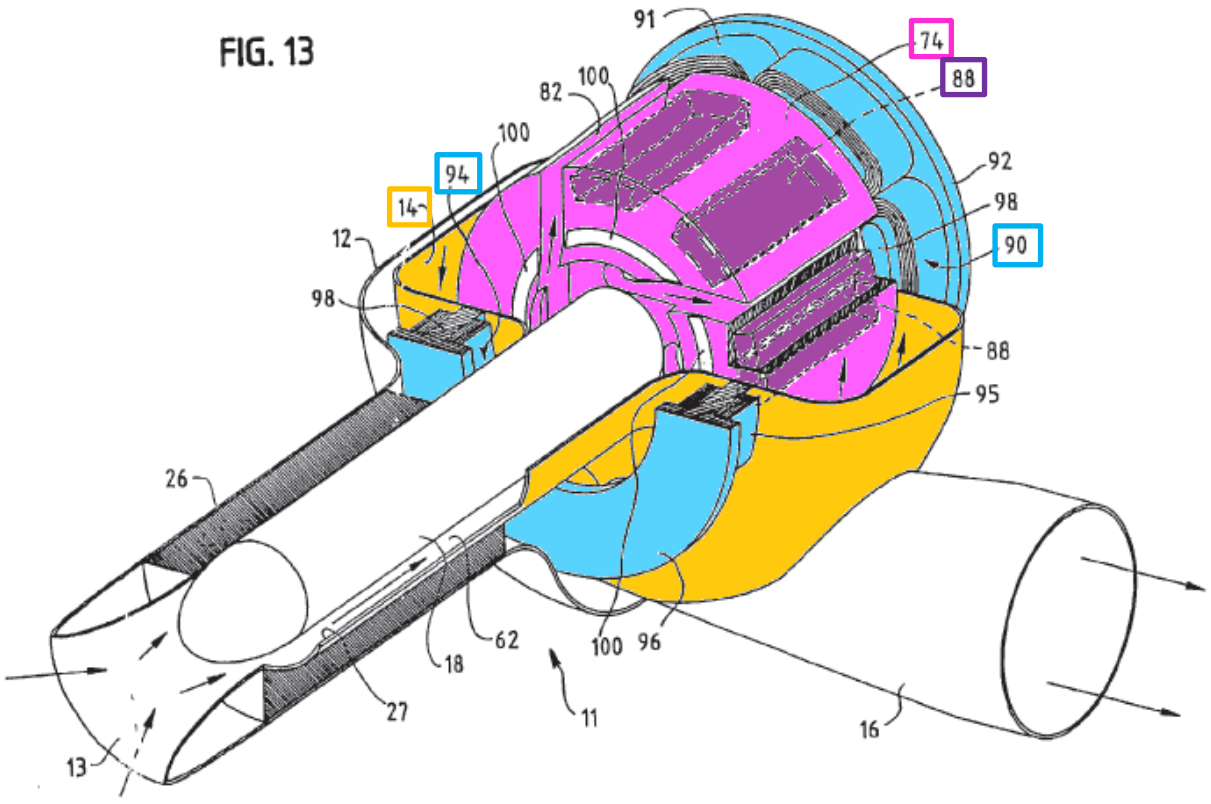
an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74."), [0050].

381. Wampler-169 further discloses that "the first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14." Ex.1008, [0083]. The "second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74," and the "windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95." Ex.1008, [0084]. In addition, "it can be seen that the motor stators 90 and 94 are placed on opposite sides of casing 14 such that each is adjacent to the pole faces of the motor rotor magnets 98." Ex.1008, [0085]; *see also* Ex.1008, [0070] ("windings 57" and "back iron 58" are "mounted on the outer surface of impeller casing 14"), [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …").

382. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008,

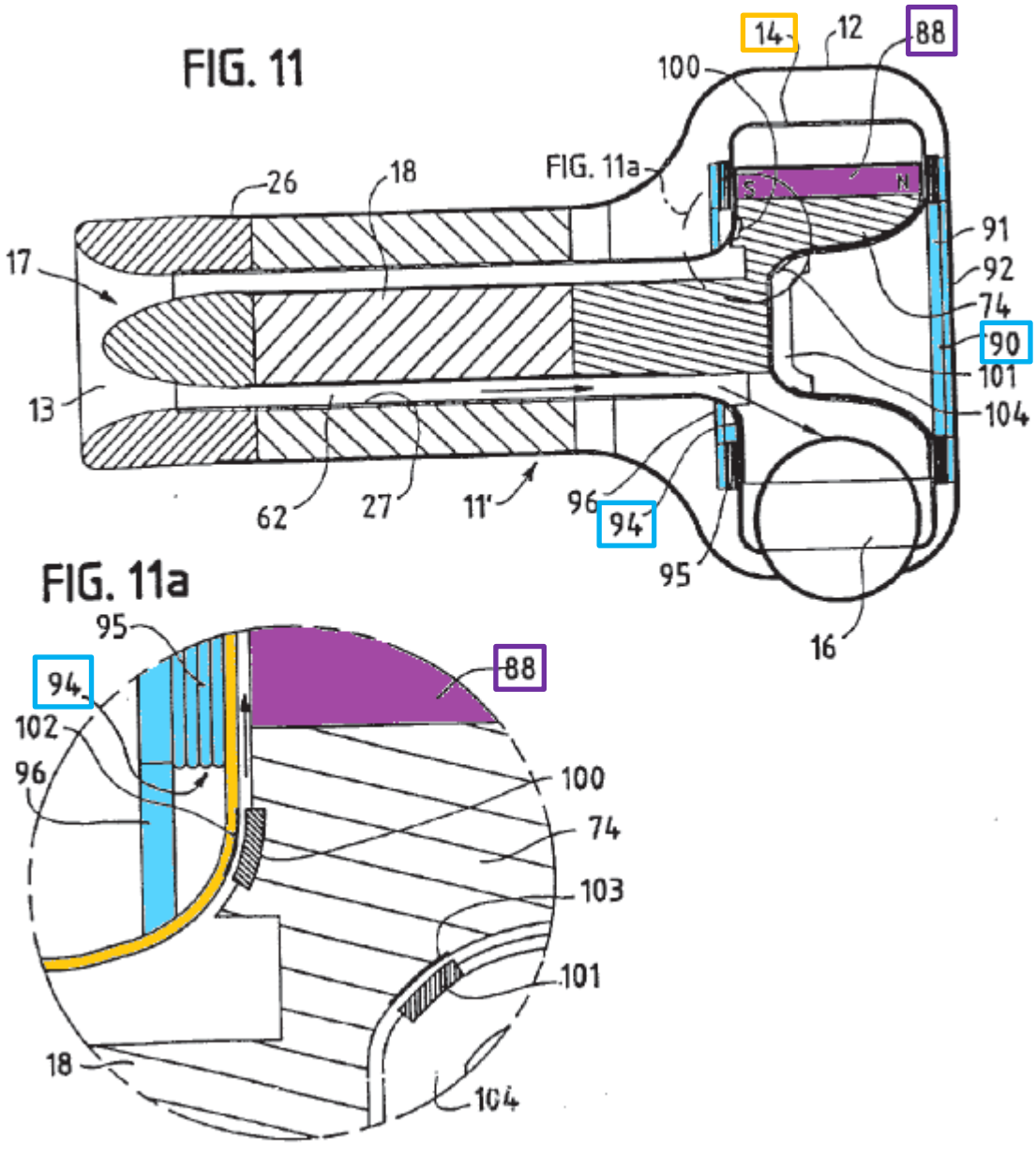
[0005], [0018], [0019], [0070], [0072], [0073], 0074]. Thus, the **second magnetic device** (e.g., "motor stators 90 and 94," Ex.1008, [0085]) is spaced apart and sealed from both the **magnetically driven rotor assembly** (e.g., "impeller 74" of the rotor, Ex.1008, [0081]) and the **first magnetic device** (e.g., the "magnetic pieces 88" imbedded in the impeller, Ex.1008, [0080]).

383. Figure 13 (annotated) of Wampler-169 illustrates a cross-sectional view of the "motor stators 90 and 94" (**light blue**) being spaced apart and sealed from the "impeller 74" (**pink**) and "magnetic pieces 88" (**purple**) by the casing 14 (**orange**):



Ex.1008, Fig. 13 (annotated) .

384. Figures 11 and 11*a* (annotated) of Wampler-169 are a cross-sectional side view of the pump 11 that illustrates the "magnetic pieces 88" (**purple**) of the impeller being spaced apart and sealed from the "motor stators 90 and 94" (**light blue**) by the casing 14 (**orange**):



Ex.1008, Figs. 11, 11*a*; *see also* Figs. 7, 8*a*, 8*b*.

385. Accordingly, Wampler-169 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly*** ("impeller 74) *is positioned, and the magnetic drive system is positioned within a **second chamber*** ("motor stators 90 and 94") *sealed from the **first chamber*** ("magnetic pieces 88")."

b. [23] The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.

386. Wampler-169 discloses claim 23. I have already explained how Wampler-169 discloses each and every element of claims 16 and 22. I incorporate that discussion into my analysis for claim 23.

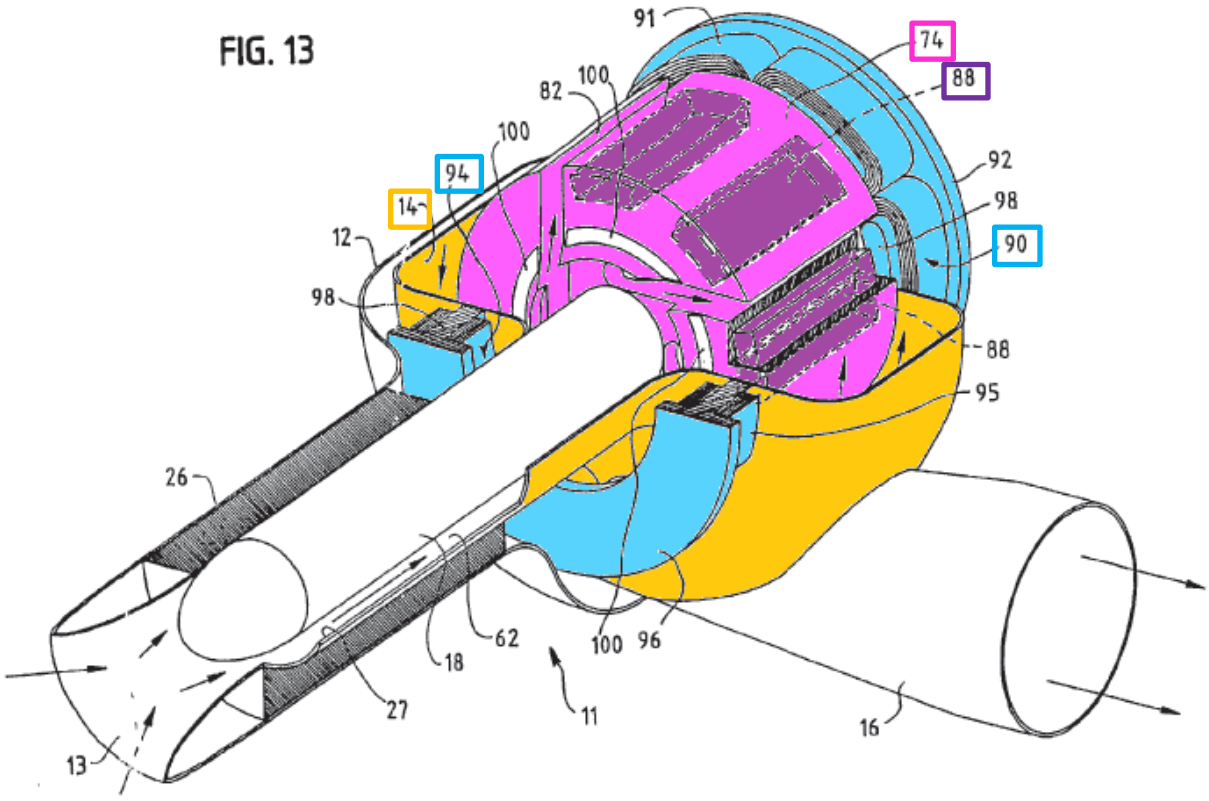
387. Wampler-169 discloses that a "*wall of the chamber walls separates the **first chamber** from the **second chamber***." As discussed with respect to element [1E], Wampler-169 discloses that the magnetically driven rotor is rotatable within **a surrounding rotor housing** (e.g., the "casing 14" or "***wall of the chamber walls***") of the pump 11 to act upon blood flowing from the **inflow tube** (e.g., "inlet tube 13") toward the **magnetically driven rotor** (e.g., "impeller 74").

388. Wampler-169 further discloses that a first motor stator 90, comprising conductive coils or motor windings 91, is located at the rear of impeller 74" and the "first motor stator 90 and back iron 92 are fixed between housing 12 and casing 14."

Ex.1008, [0083]. "A second motor stator 94, comprising windings 95, is positioned on the forward side of impeller 74" and "windings 95 are fixed to casing 14 and a ring of back iron 96 is positioned forward of windings 95." Ex.1008, [0084]; *see also* Ex.1008, [0018] ("A ring of back iron is fixed to the casing to aid in completing a flux return path for the permanent magnets …"). As mentioned previously, the "pump rotor 17 is located within housing 12, within casing 14, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to impeller 74." Ex.1008, [0081]. Thus, the "casing 14" provides a sealing wall between the motor stators 90 and 94 and the magnetic pieces 88 imbedded in the impeller 74.

389. Indeed, the pump 11 described in Wampler-169 is a "sealless rotary blood pump." Ex.1008, [0050]. Wampler-169 describes problems in the art at the time with the short life of driveshaft seals in prior art LVADs, contributing to premature failure of the pump and the possibility of causing embolisms. Ex.1008, [0005]. The pump 11 of Wampler-169 "eliminat[es] the necessity for a driveshaft seal" by the use of the magnetic elements of the electric motor, such that torque is transferred to the drive the pump without contact between components. Ex.1008, [0005], [0018], [0019], [0070], [0072], [0073], 0074].

390. Figure 13 (annotated) illustrates that the "casing 14" (**orange**) provides a sealing wall between the "magnetic pieces" (**purple**) of the "impeller 74" (**pink**) and the motor stators 90 and 94 (**light blue**):



Ex.1008, Fig. 13 (annotated).

391. Accordingly, Wampler-169 discloses that a "***wall of the chamber walls*** *separates the* ***first chamber*** ("magnetic pieces 88") *from the* ***second chamber*** ("motor stators 90 and 94")."

10. Claim 24

a. [24] The system of claim 16, wherein the first magnetic device comprises a permanent magnet.

392. Wampler-169 discloses claim 24. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 24.

393. Wampler-169 discloses that "*the **first magnetic device** comprises a permanent magnet*."

394. This element is invalid for the same reasons discussed above in [1C] and [1F], thus, I incorporate that discussion into my analysis here.

395. Accordingly, Wampler-169 discloses that "*the **first magnetic device** comprises a permanent magnet*."

11. Claim 26

a. [26] The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

396. Wampler-169 discloses claim 26. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 26.

397. Wampler-169 discloses "*one or more sensors configured to deliver feedback signals to the **external control unit***."

398. This element is invalid for the same reasons discussed above in [7], thus, I incorporate that discussion into my analysis here.

399. Accordingly, Wampler-169 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit*** ("controller 59")."

12. Claim 28

a. [28] The system of claim 16, wherein the heart assist pump device is a catheter device.

400. Wampler-169 discloses claim 28. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 28.

401. Wampler-169 discloses that "*the* ***heart assist pump device*** *is a catheter device*."

402. This element is invalid for the same reasons discussed above in [10], thus, I incorporate that discussion into my analysis here.

403. Accordingly, Wampler-169 discloses that "*the* ***heart assist pump device*** ("blood pump 11"") *is a catheter device*."

B. Ground 2: Bourque-2001 in view of Wampler-169 Renders Obvious Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent

1. Claim 1

i. [1PRE] A system for assisting the blood circulation of a heart, comprising:

404. To the extent that the preamble is a limitation, Bourque-2001 discloses "*a system for assisting the blood circulation of a* ***heart***."

405. For example, Bourque-2001 discloses the design and testing of a "long-term, compact left ventricular assist device (LVAD) ['*for assisting the blood circulation of a heart*]," known as the HeartMate III. Ex.1007 at 401, 405 ("reliable device to treat CHF"). Bourque-2001 discloses that LVADs, like the HeartMate III and its predecessors (e.g., HeartMate II), have "provided significant benefit to certain [congestive heart failure] patients" by "seek[ing] to ameliorate increases in mortality due to the divergence of the increasing population of those awaiting cardiac transplant and the somewhat dwindling availability of organs." Ex.1007 at 401. Bourque-2001 further describes that the HeartMate III is a "continuous flow-type pump," which serves to assist the pumping of blood from the left ventricle to the aorta of a heart. The HeartMate III was designed "to achieve a design point of 7 L/min against 135 mm Hg at high hydrodynamic efficiency (30%) and to be capable of up to 10 L/min under such a load." Ex.1007 at 401. The HeartMate III LVAD

(**blue**) in its implanted configuration in the heart (**red**) of a body is illustrated in Figure 3, annotated:

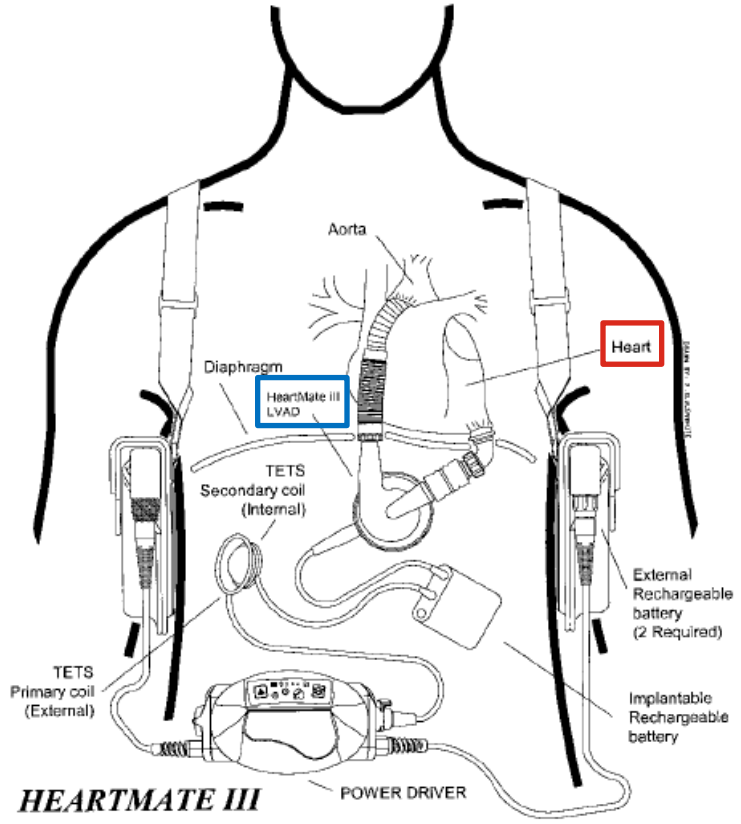


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

406. Accordingly, Bourque-2001 discloses "*a system for assisting the blood circulation of a* ***heart*** ("reliable device to treat CHF"). "

407. Further, I have reviewed the Patent Owner's initial response to Abbott's invalidity contentions served in the parallel litigation, and I understand that the PO concedes that Bourque-2001 discloses this element. I have been informed that the

rules required the PO to admit or deny whether an element was present in the prior art. Miracor admitted that Bourque-2001 discloses this limitation. *See* Ex.1026, at pp. F-1 2 (Miracor Responsive Chart for U.S. Patent No. 11,754,077 over Bourque-2001).

ii. [1A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart

408. Bourque-2001 discloses "*a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart*."

409. The 077 Patent does not define the term "delivering a heart assist pump device to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "delivering a heart assist pump device to the heart" includes "implant[ing]…a suction end of an inflow tube…inserted into a left ventricle of a patient's heart and a magnetically drive rotor…position outside the ventricle." *See* Ex.1019, (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "delivering a heart assist pump device to the heart."

410. Accordingly, the HeartMate III "left ventricular assist device (LVAD)" described in Bourque-2001 is "***a heart assist pump device***" that is delivered to the heart. Ex.1007, at 401. Bourque-2001 discloses that "[t]he advent of the left ventricular assist device (LVAD) has provided significant benefit to certain [congestive heart failure] patients since becoming clinically available. Ex.1007, at 401.

411. The HeartMate III includes an ***inflow tube*** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) *defining a blood inflow path…insertable into a ventricle of the heart* "[i]s implanted with routine surgical techniques via left ventricular apical cannulation." Ex.1007 at 401, 403, Fig. 4. A "cannula" in this context is a tube that is inserted in the left ventricle for the inflow of blood to the pump. The HeartMate III LVAD (**blue**), including the inflow subassembly (**green**), in its implanted configuration in the heart (**red**) of a body is illustrated in Figure 3, annotated:

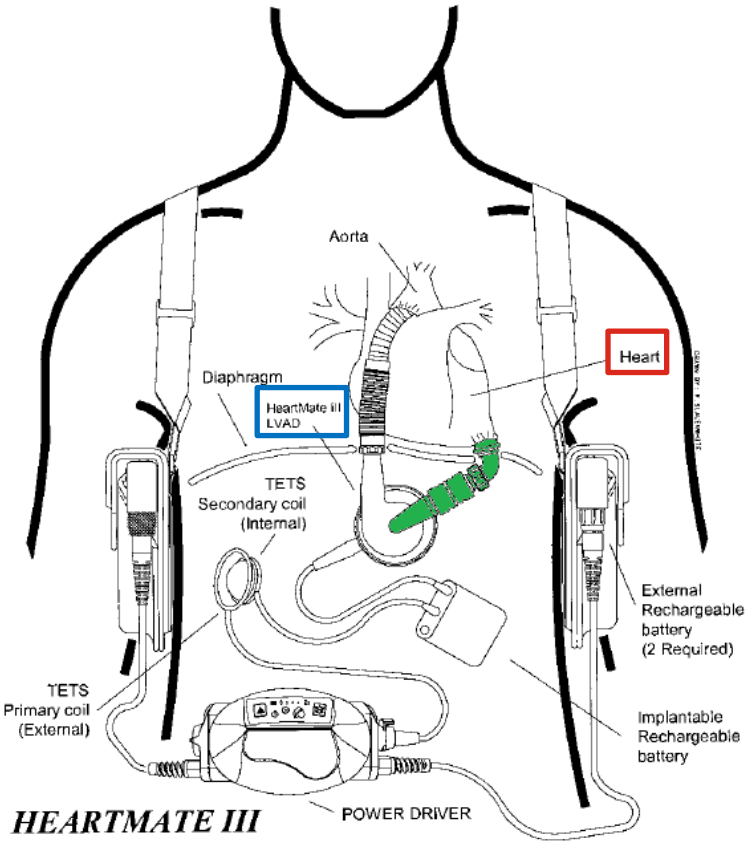
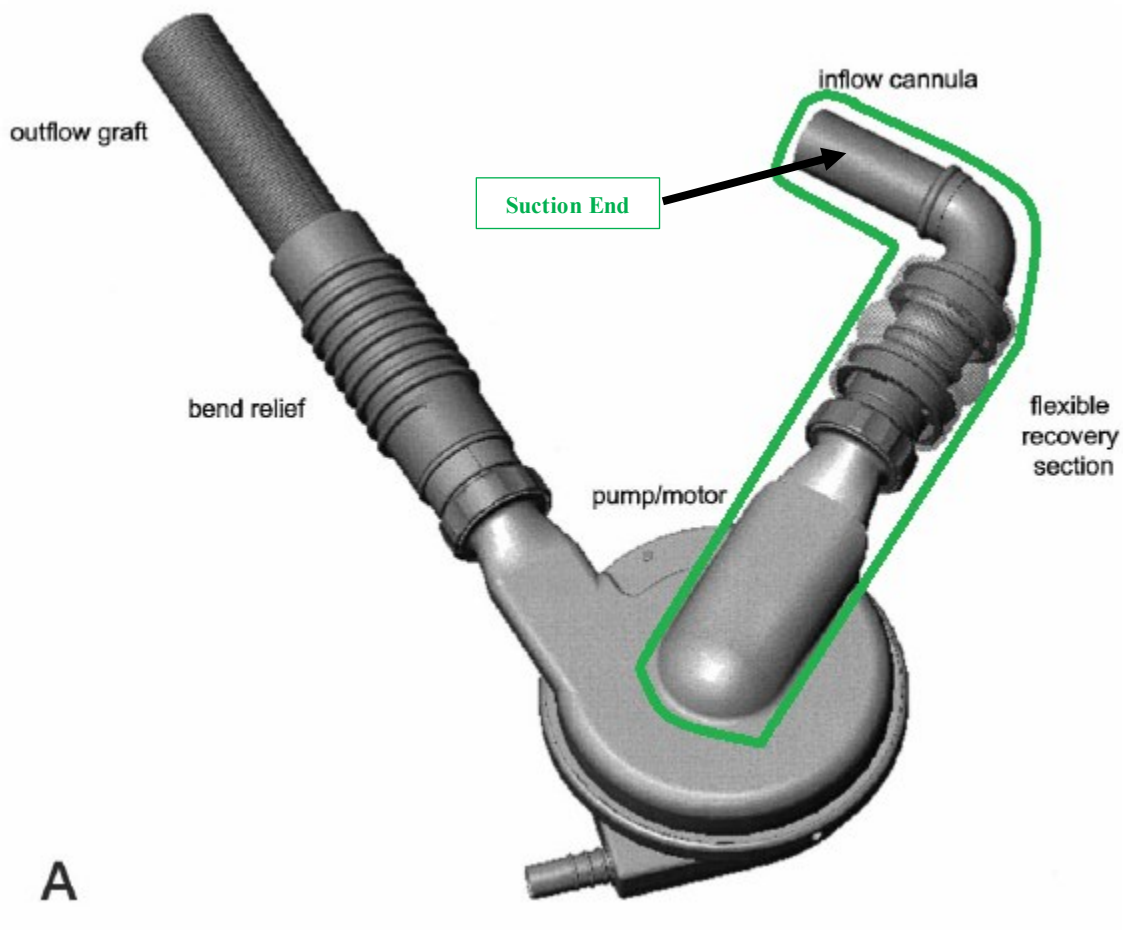


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

412. Figure 1A of Bourque-2001 illustrates an overall view of the HeartMate III pump, which includes the LV cannula of the inflow tube (cannula) (**green**) that has a "suction end" (annotated):



Ex.1007, Fig. 1A.

413. Accordingly, Bourque-2001 discloses "***a heart assist pump device*** ("HeartMate III LVAD") *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** ("an inflow subassembly that includes a left ventricular (LV) cannula") *and having a suction end insertable into* ***a ventricle of the heart*** ("left ventricular apical cannulation")."

iii. [1B] a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle

414. Bourque-2001 discloses that the "***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow tube*** *and to be spaced apart from the suction end when the* ***suction end of the inflow tube*** *is inserted into the* ***ventricle***."

415. The HeartMate III pump includes "a rotor that includes an impeller and passively magnetic elements," which is a "***magnetically driven rotor assembly***." Ex.1007 at 401. The HeartMate III pump's rotor *is spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle*, because Bourque-2001 describes that the HeartMate III includes "a lower housing that includes the lower half of the volute and a cavity for the rotor, in which the motor is enclosed." Ex.1007 at 401.

416. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described in Bourque-2001. Ex.1007 at Abstract ("A long-term compact left ventricular assist device (LVAD), the HeartMate III, has been designed and fabricated, featuring **a centrifugal pump with a magnetically levitated**

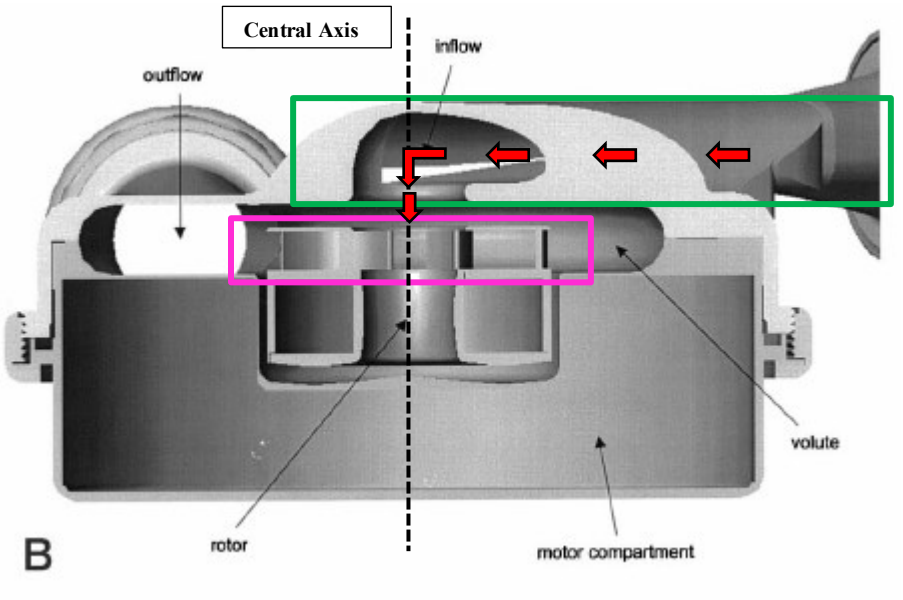
rotor."). I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller of the "rotor" of the "HeartMate 3" to the "rotor" element recited in Claim 1. Ex.1019, at pp. 5 (Complaint, Ex. 13). For the purposes of my analysis, I map the limitation of a "rotor" to the "impeller" portion of the rotor described in Bourque-2001 in the same way.

417. As detailed below with respect to element [1C], there exist permanent magnetic segments **magnetic pieces 88**, which are rigidly coupled and axially adjacent **impeller 74**.

418. Thus, the **impeller 74** together with the **magnetic pieces 88** described in Bourque-2001 are a **magnetically driven rotor assembly** because together they form a rotor driven by the force generated by the electromagnetic field created between the "passively magnetic elements" and the "actively controlled" magnetic elements of the motor. *See infra* Sections X.B.1.viii and X.B.2.b; Ex.1007 at 402; Ex.1007 at 402-403 ("HeartMate III motor includes drive and levitation in a single magnetic structure as shown in Figure 4. The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom and actively magnetically levitated in the remaining degrees of freedom."); *see also* Ex.1007 at 401 ("[T]he pump has no mechanical bearings. The rotor is magnetically

suspended, eliminating contact between the moving parts and consequently extending wear life indefinitely.").

419. For components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis") in space. The HeartMate III pump described in Bourque-2001 has a central axis that is configured in axial alignment with the **inflow tube** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) so as to provide the flow of blood to the ***magnetically driven rotor assembly*** ("impeller" and "passively magnetic elements" of the rotor, Ex.1007 at 401). For example, Figure 1B (annotated) illustrates the alignment of the impeller of the rotor (**pink**) and the LV cannula of the inflow subassembly (**green**) of the HeartMate III along a central axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated).

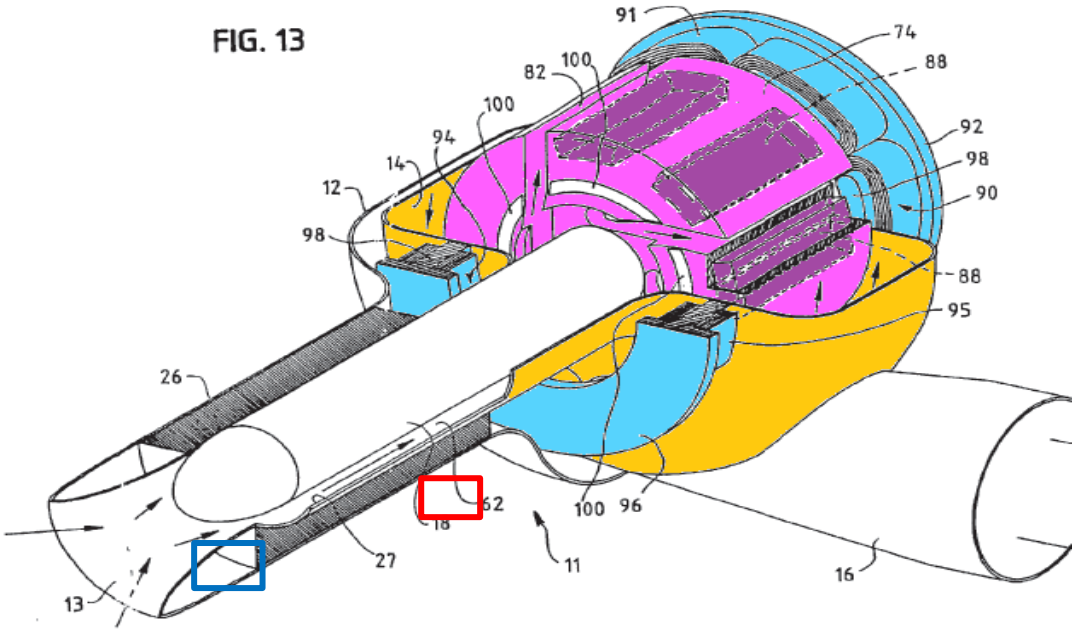
420. While the inflow subassembly of the HeartMate III includes an "elbow" through which blood flows from the LV cannula to the impeller, the portion of the inflow subassembly where blood flows into the pump chamber is axially aligned along the central axis with the impeller of the pump, as illustrated by the red arrows in Figure 1B above.

421. Indeed, the HeartMate III pump described in Bourque-2001 is a **centrifugal** pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

422. Accordingly, Bourque-2001 discloses that the "***magnetically driven rotor assembly*** ("impeller") *configured to be axially aligned with the* ***inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula") *and to be spaced apart from the suction end when the* ***suction end of the inflow tube*** *is inserted into the* ***ventricle***."

423. To the extent that Bourque-2001 does not expressly disclose an "*axially aligned…inflow tube*," it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 in view of Wampler-169 to axially align the LV cannula with the impeller of the rotor for numerous reasons as discussed below in Section X.B.13636. Wampler-169 appreciated that "[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation." Ex.1008, [0076]. "Owing to the axial inflow and radial outflow of the pump," which is a characteristic feature of centrifugal pumps including the Bourque 2001 device, Wampler-169 explains that "a 90 degree redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting**." Ex.1008, [0076]. With this design, "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076]. Consequently, "[t]he inlet tube 16 serves as the inflow cannula and is placed into the

apex of the left ventricle 64," thereby eliminating the need for any elbow or additional inflow assembly, as shown below. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the inlet tube 13 (**green**) of the pump 11 (**blue**) implanted within the left ventricle 64 (**red**) of the heart:



Ex.1008, Fig. 5 (annotated).

424. In the combination of Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 (hereinafter Bourque/Wampler), the *axially aligned inflow tube* would have been implemented at the same location as the Bourque-2001 inflow tube so that "[t]he inlet tube…serves as the inflow cannula and is placed into the apex of the left ventricle" as taught by Wampler-169. Ex.1008, [0076]. As shown, Wampler-169 appreciated that the "[t]he centrifugal design of the pump

allows…a 90 degree redirection of the blood [] without the necessity of a flow-restrictive elbow fitting." Ex.1008, [0076].

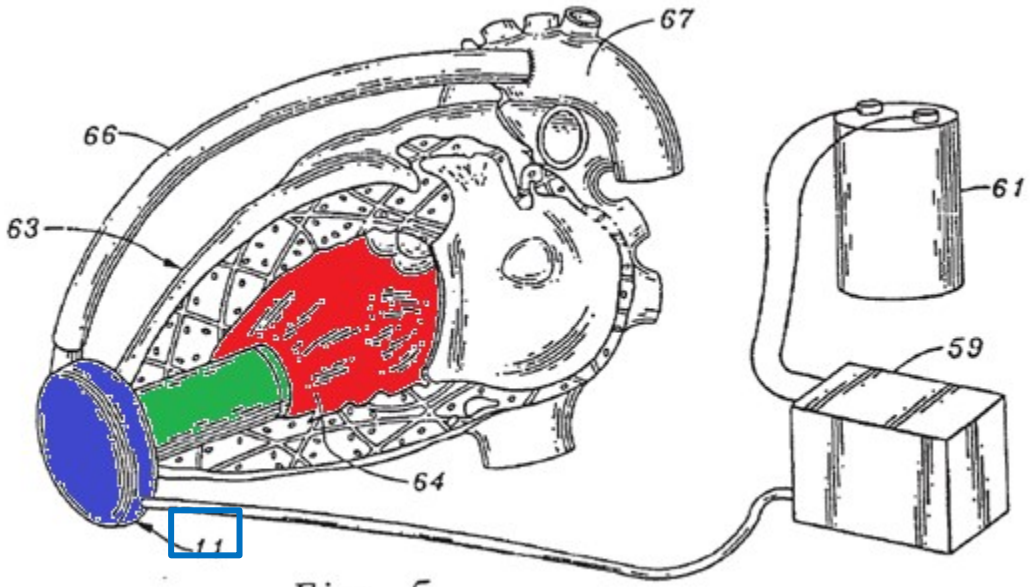


Fig. 5

Ex.1008, Fig. 5.

425. A POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful because an author of Bourque-2001 taught that this specific modification was "not complex" and was "well-known in the art." Ex.1018 at 6:62-7:5. Victor L. Poirier is one of the engineers of Bourque-2001 HeartMate III device, co-author of Bourque-2001 reference, and also the inventor of U.S. Patent No. 6,050,975 (Ex.1018), assigned to Thoratec. The 975

Patent describes that its centrifugal pump (e.g., Bourque-2001 HeartMate III) can be modified to use this inflow cannula from the axial flow blood pump:

> [P]ump 400 may be modified to incorporate… inflow cannula apical tube 45…The modifications required are not complex and are well-known in the art.

Ex.1018 at 6:62-7:5. Because the 975 patent teaches that modifying the Bourque-2001 with "an inflow cannula apical tube 45" is "not complex," a POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful.

426. Accordingly, Bourque-2001 discloses and/or Bourque-2001 in view of Wampler-169 renders obvious that the "***magnetically driven rotor assembly*** ("impeller") *configured to be axially aligned with the* ***inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007; "inlet tube [13] serves as the inflow cannula," Ex.1008) *and to be spaced apart from the suction end when the* ***suction end of the inflow tube*** *is inserted into the* ***ventricle***."

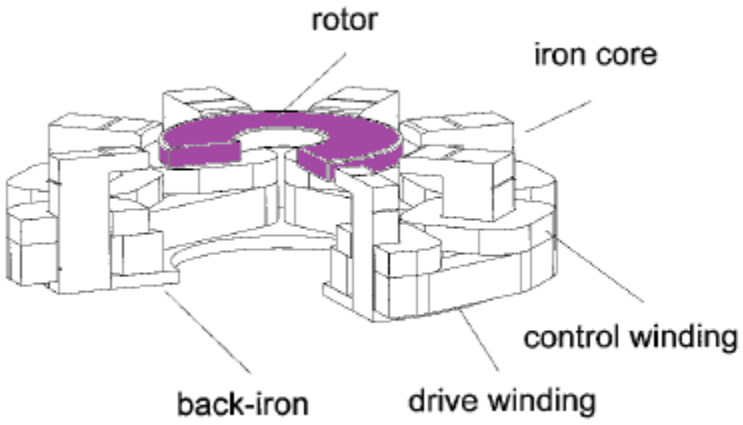
iv. [1C] the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor

427. Bourque-2001 discloses the **magnetically driven rotor assembly** "*comprising a* ***first magnetic device*** *that is rigidly coupled to and axially adjacent to a* ***rotor.***"

428. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **passively magnetic elements** which are rigidly coupled and axially adjacent the **impeller**.

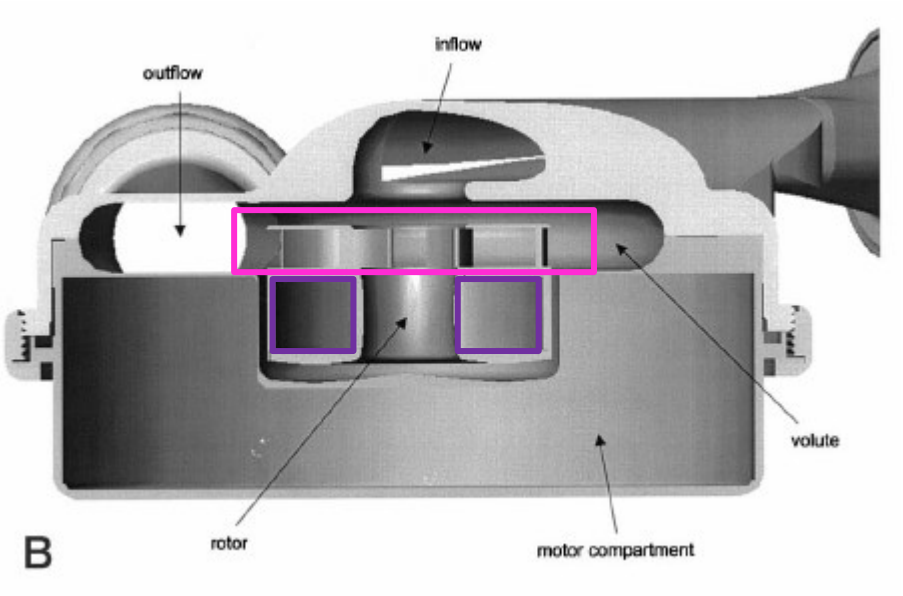
429. As will be discussed with respect to elements [1G] and [1J], the rotation of the passively magnetic elements of the rotor causes rotation of the impeller of the rotor, resulting in the flow path of blood through the inflow section, to the impeller of the rotor, and finally "exit[ing] the backswept blades of the impeller into a volute…and directing toward the outflow of the HeartMate III. Ex.1007 at 402; *see infra* Sections X.B.1.viii, X.B.1.xi, and X.B.1.xii. A POSITA would understand the "impeller" and the "passively magnetic elements" to be "rigidly coupled" to one another such that they are locked in relative rotation so that the magnetic force applied to passively magnetic elements of the rotor may effect rotation of the impeller.

430. Figure 4 of Bourque-2001 depicts the passively magnetic element of the rotor (**purple**) of the HeartMate III:



Ex.1007, Fig. 4 (annotated).

431. Bourque-2001 describes that the "rotor that includes an impeller and passively magnetic elements," and Figure 1B of Bourque-2001 illustrates the rigid coupling between the impeller (**pink**) and the passively magnetic element (**purple**).



Ex.1007 at 401, Fig. 1B (annotated).

432. Further, in order to provide the torque necessary to rotate the impeller, the "**passively magnetic elements**" are axially adjacent (situated next to each other on the same axis) to the **impeller** such that, when the magnetic force is applied to rotate the "passively magnetic elements," the impeller may then rotate about its axis. Ex.1007 at 401-402 ("the stiffness of the magnetic suspension…in the axial direction" is a feature of "the levitation system's capacity to counteract imposed deviations of rotor position"). Ex.1007 at 401.

433. Accordingly, Bourque-2001 discloses the ***magnetically driven rotor assembly*** ("impeller") "*comprising a **first magnetic device*** ("passively magnetic elements") *that is rigidly coupled to and axially adjacent to a **rotor***."

v. [1D] [the rotor] having guide surfaces to produce centrifugal flow components

434. Bourque-2001 discloses that the **rotor** "*having guide surfaces to produce centrifugal flow components*."

435. Bourque-2001 discloses that the "impeller" of the rotor includes a "shroud (i.e., the cover across the top of the blades on the rotor)" and impeller "blades" having "leading edges" and "trailing edges." Ex.1007 at 402. Each of these components of the impeller is a "guide surface," which serves to direct the flow of blood within the centrifugal pump to the outflow subassembly. That is, "[a]n opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades." Ex.1007 at 402. "The flow exits the backswept blades of the impeller into a volute of uniformly increasing width, which terminates at a cutwater, peeling off most of the flow and directing toward the outflow." Ex.1007 at 402; *see also* Ex.1007 at 402 ("The pump components were designed to achieve the desired flow paths, accommodate the motor, and provide convenient, reliable connections in the simplest, most cost effective way.").

436. Indeed, the HeartMate III pump described in Bourque-2001 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, the production of centrifugal flow components by the components of the impeller are a characteristic feature of a centrifugal pump.

437. Accordingly, Bourque-2001 discloses the **rotor** ("impeller") "*having guide surfaces to produce centrifugal flow components*."

vi. [1E] the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor

438. Bourque-2001 discloses "*the **magnetically driven rotor assembly** being rotatable about a **central axis** within **a surrounding stationary housing** to act upon blood flowing from the **inflow tube** to the **rotor**.*"

439. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **passively magnetic elements** which are rigidly coupled and axially adjacent the **impeller**.

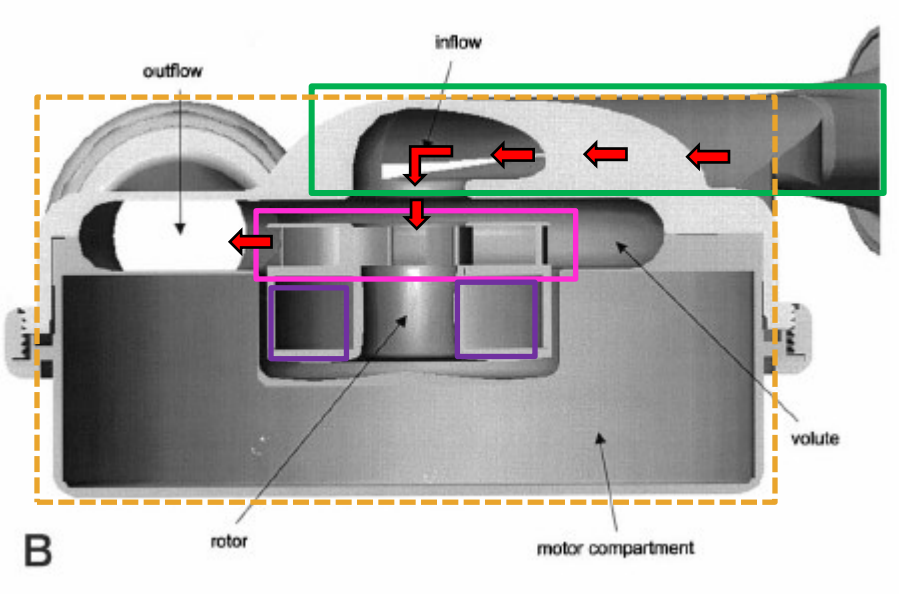
440. Further, Bourque-2001 discloses that the "HeartMate III pump (Figures 1 and 2) comprises an upper housing that includes the inflow and outflow channels and the upper half of the volute" and "a lower housing that includes the lower half

of the volute and a cavity for the rotor, in which the motor is enclosed." Ex.1007 at 401. The HeartMate III pump further includes a "screw ring to clamp together the upper and lower housings." Ex.1007 at 401. Thus, the "upper housing" and "lower housing" of the HeartMate III, when clamped by the "screw ring," form a ***surrounding stationary housing***, which includes "a cavity for the rotor" so that the ***magnetically driven rotor assembly*** ("impeller" and "passively magnetic pieces") *is rotatable within* it. Ex.1007 at 401

441. Bourque-2001 further discloses the flow path of blood through the inflow section, and thereby to the impeller of the rotor of the HeartMate III. "An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller" to allow the impeller *to act upon blood flowing from the* ***inflow tube*** *to the* ***rotor***. Ex.1007 at 4021; *see also* Ex.1007 at 403 ("The pump was prescribed to run at 3,500 rpm perioperatively," i.e., 3,500 revolutions per minute).

442. Thus, the **magnetically driven rotor assembly** (e.g., the "impeller" and "passively magnetic pieces" of the rotor, Ex.1007 at 401) is rotatable to act upon blood flowing from the **inflow tube** toward the **magnetically driven rotor** when "fluid leave[s] the inflow conduit to enter the impeller." Ex.1007 at 402.

443. Figure 1B (annotated) illustrates the impeller of the rotor (**pink**) and the passively magnetic elements of the rotor (**purple**) rotatable within the "upper housing and lower housing" (**orange**) of the HeartMate III pump to act upon blood flowing (**red** arrows) from the inflow subassembly (**green**) toward the impeller:



Ex.1007, Fig. 1B.

444. Thus, the "upper housing and "lower housing" of the HeartMate III, when clamped together by the "screw ring," form *the **surrounding stationary housing*** which houses the ***first magnetic device*** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401).

445. Accordingly, Bourque-2001 discloses that "*the **magnetically driven rotor assembly** being rotatable about a **central axis** within **a surrounding stationary***

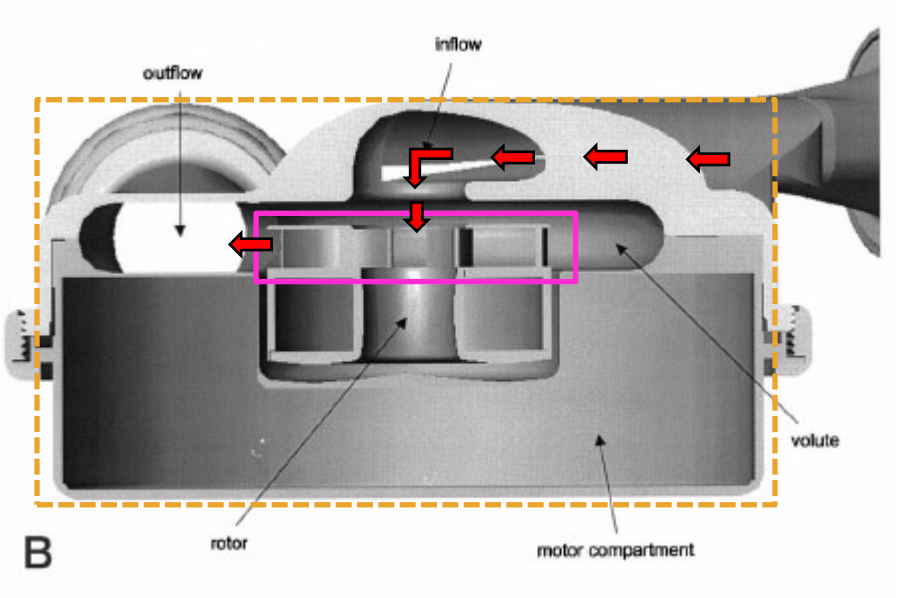
housing ("upper housing and lower housing") *to act upon blood flowing from the* ***inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula") *to the* ***rotor*** ("impeller")."

vii. [1F] while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;

446. Bourque-2001 discloses that "*the* ***magnetically driven rotor assembly*** *is entirely spaced apart from the* ***stationary housing*** *by a gap sized for passage of the blood.*"

447. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **passively magnetic elements** which are rigidly coupled and axially adjacent the **impeller**.

448. In addition, Bourque-2001 discloses that in response to rotation of the impeller and embedded passively magnetic elements, which is the **magnetically driven rotor assembly**, remain entirely spaced apart from the **stationary housing** (e.g., "***gaps*** permit up to 7× gravitational loads in any direction ***without contact between the rotor and housing***"):



Ex.1007, Fig. 1B.

449. In describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the

rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing."):

450. Accordingly, Bourque-2001 discloses that "*the **magnetically driven rotor assembly*** ("impeller") *is entirely spaced apart from the **stationary housing*** ("upper housing and lower housing") *by a gap sized for passage of the blood*."

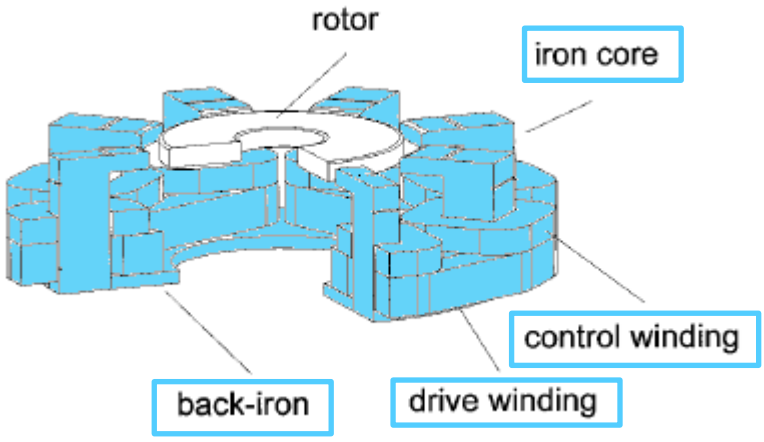
viii. [1G] a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device

451. Bourque-2001 discloses "*a **second magnetic device** axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** via a magneto coupling with the **first magnetic device***."

452. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **passively magnetic pieces** which are rigidly coupled and axially adjacent the **impeller**.

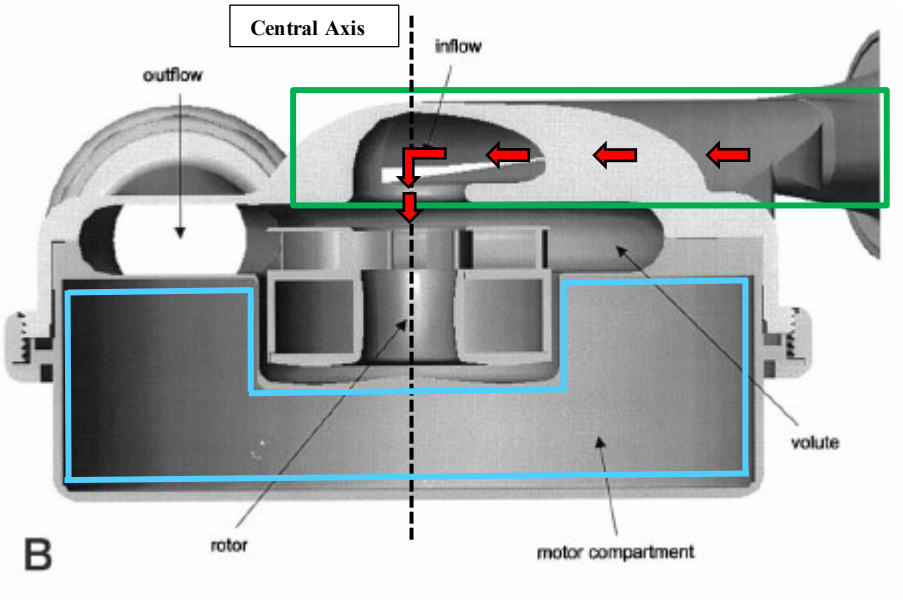
453. Bourque-2001 discloses that "[t]he very simple main flow path is a consequence of the motor's "J" core configuration (i.e., the stator laminations are J shaped), which places an imaginary plane near the mid-height of the pump, below which are confined the motor and levitation elements, and above which the hydrodynamic elements are permitted free reign"). A "stator" is a commonly used component of an electric motor, typically made of iron or an electrically conductive coil, that remains static and creates a rotating magnetic field when an electric current is supplied, which thereby causes rotation of a rotor. The "motor" comprising the "stator laminations," "iron core," "drive winding," "control winding," and "back-iron" described in Bourque-2001 are a **second magnetic device** as recited in Claim 1.

454. Figure 4 of Bourque-2001 depicts the "J" shaped stator laminations, control winding, drive winding, iron core, and back-iron comprising the "motor" (**light blue**) of the HeartMate III pump:

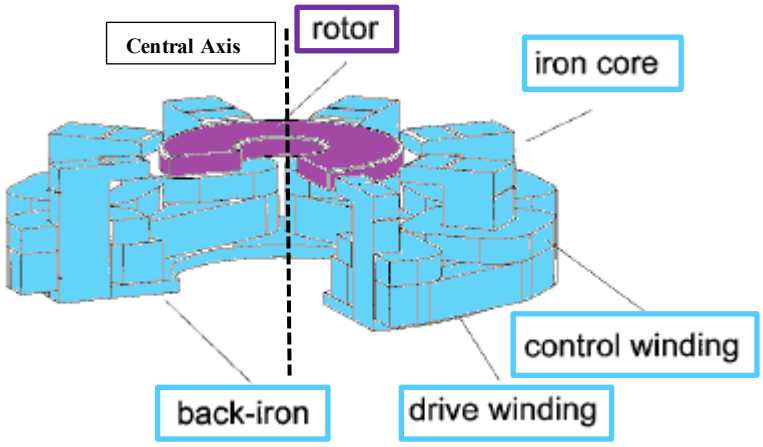


Ex.1007, Fig. 4 (annotated).

455. Figure 1B (annotated) illustrates the alignment of the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") in the motor compartment and the LV cannula of the inflow subassembly (**green**) of the HeartMate III along a central axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated). Note that Figure 1B is a cross-sectional view of the HeartMate III and the stator laminations are understood to radially surround the passively magnetic elements of the rotor. The axial alignment of the components of the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**) (which is in turn axially aligned with the impeller of the rotor and LV cannula of the inflow subassembly (*see supra* Section [1B])) can be seen in Figure 4 (annotated):



Ex.1007, Fig. 4 (annotated).

456. As discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is correct. *See* Ex.1019.

457. Accordingly, based on the Patent Owner's understanding of the term, Bourque-2001 describes a magneto coupling between the **second magnetic device**

(e.g., the "motor," including the "stator laminations" and "windings," Ex.1007 at 404, Fig. 4) and the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

458. Figure 5 (annotated) of Bourque-2001 illustrates the magneto coupling between the "passively magnetic elements" of the rotor (**purple**) and the "stator laminations" of the motor (**light blue**):

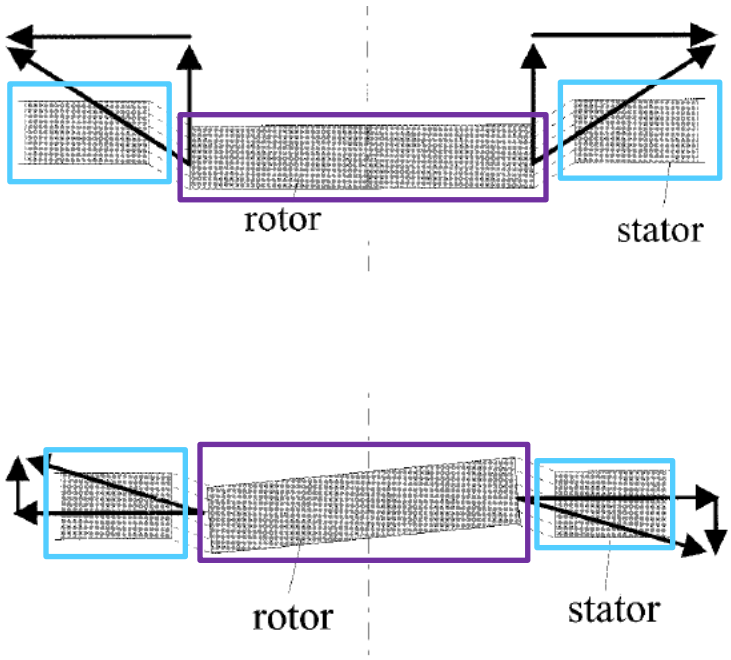


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

459. As discussed with respect to element [1F], the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) is rigidly coupled to the **magnetically driven rotor assembly** (e.g., the "impeller" of the rotor). Bourque-2001 further discloses how the motor impacts the rate of blood flow produced by the **magnetically driven rotor assembly** (e.g., the "impeller" of the rotor), confirming that the **second magnetic device** (e.g., the "motor") of the HeartMate III is positioned to magnetically drive rotation of the **magnetically driven rotor assembly** via the electromagnetic field applied to the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor). Ex.1007 at 403 ("Note

that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

460. Accordingly, Bourque-2001 discloses "*a **second magnetic device*** ("motor") *axially aligned with the **inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula") *and positioned to magnetically drive rotation of the **magnetically driven rotor assembly*** ("impeller" and "passively magnetic elements") *via a magneto coupling with the **first magnetic device*** ("passively magnetic elements")."

461. To the extent that Bourque-2001 does not expressly disclose the **second magnetic device**, it would have been obvious to a POSITA as of February 27, 2007 to modify the inflow subassembly of the HeartMate III described in Bourque-2001 to axially align the LV cannula with the motor for numerous reasons. *See supra* element [1B], Section X.B.1.iii.

462. Accordingly, Bourque-2001 in view of Wampler-169 discloses and/or renders obvious that "*a **second magnetic device*** ("motor") *axially aligned with the **inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula")

and positioned to magnetically drive rotation of the ***magnetically driven rotor assembly*** (“impeller”) *via a magneto coupling with the* ***first magnetic device*** (“passively magnetic elements”).”

ix. [1H] while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly

463. Bourque-2001 discloses that the **second magnetic device** is positioned according to element [1H] “*while being spaced apart and sealed from both the* ***rotor*** *and the* ***first magnetic device*** *of the* ***magnetically driven rotor assembly***”

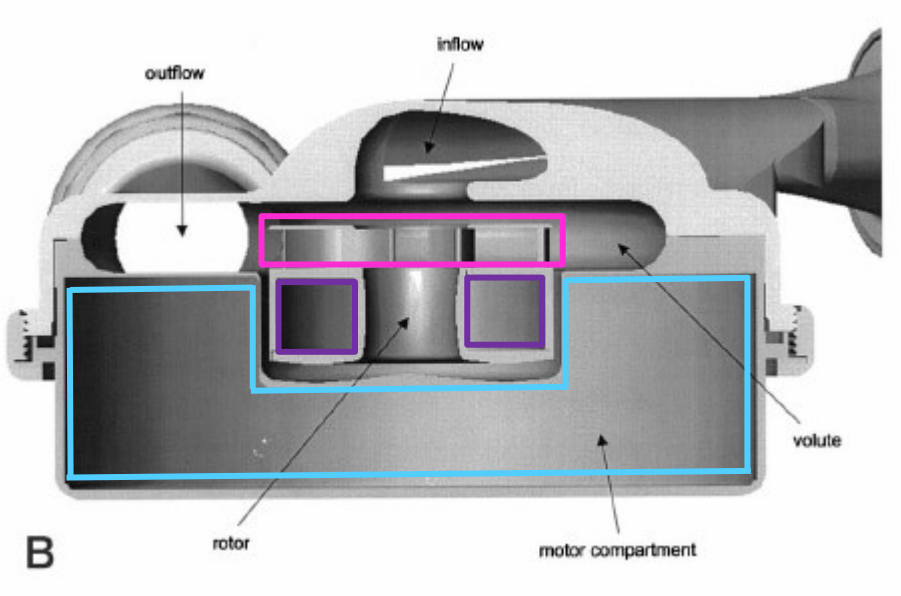
464. For example, Bourque-2001 discloses that the HeartMate III’s “rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.” Ex.1007 at 401. The HeartMate III has a “lower housing” that includes “a cavity for the rotor” and “in which the motor is enclosed.” Ex.1007 at 401; *see also* Ex.1007 at 404 (“It was a fundamental goal of the HeartMate III mechanical design…to enclose a sophisticated motor.”), 402 (“installing the motors in the pump lower housings”).

465. Bourque-2001 further discloses that the **second magnetic device** (e.g., the “motor”) is sealed by “titanium surfaces…textured in the same way as the HeartMate and HeartMate II,…intended to promote the development of a stable,

adherent pseudoneointima immediately upon contact with blood, thereby insulating subsequent blood flow from contact with nonbiologic materials and reducing the risk of thromboembolism." Bourque-2001 at 401 (citations omitted).

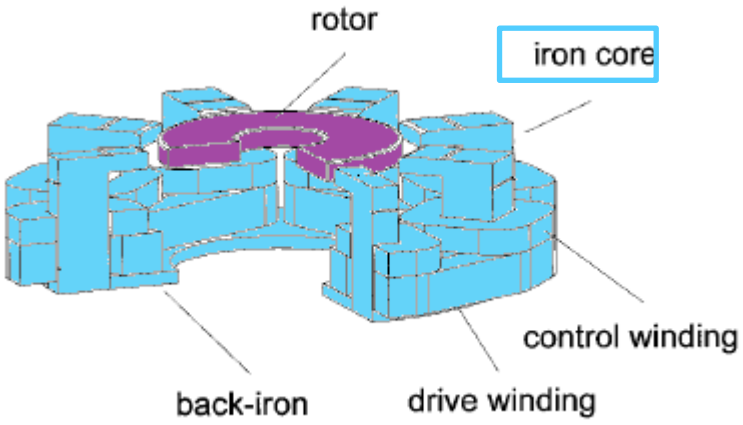
466. In describing the blood flow path, Bourque-2001 discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

467. Figure 1B (annotated) illustrates that the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") is spaced apart and sealed from the impeller of the rotor (**pink**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007 at Fig. 1B (annotated). Bourque-2001 also discloses that these elements are "*sealed…by at least one sealing wall*" because it discloses that "the pump components were designed to achieve the desired flow paths"—from the "inflow section," through the impeller, "toward the outflow." Ex.1007, 402.

468. Figures 4 and 5 also illustrate the spacing and sealing between the "stator laminations" of the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007, Fig. 4.

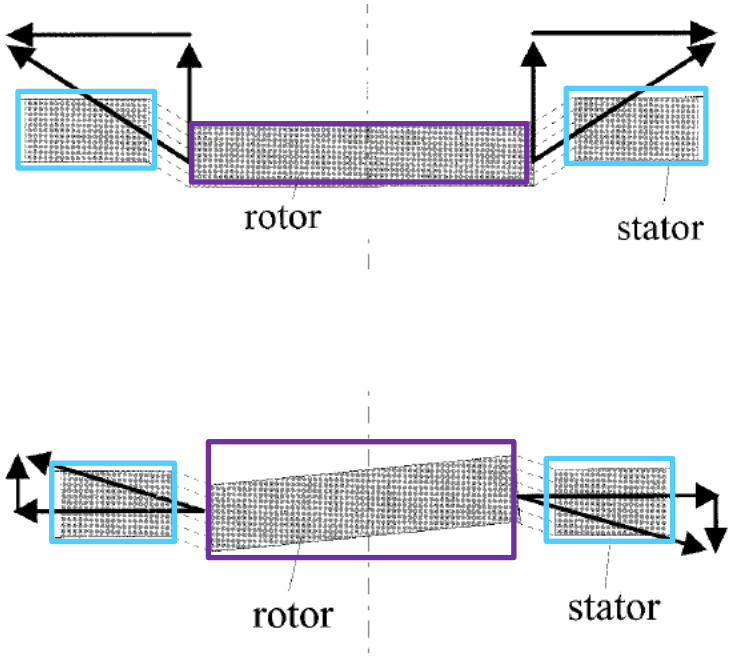


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

469. Accordingly, Bourque-2001 that the **second magnetic device** ("motor") is positioned according to element [1H] "*while being spaced apart and*

sealed from both the ***rotor*** (“impeller”) *and the* ***first magnetic device*** (“passively magnetic elements”) *of the* ***magnetically driven rotor assembly***.”

x. [1I] the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor

470. Bourque-2001 discloses that “*the* ***second magnetic device*** *being positioned axially spaced apart from the guide surfaces of the* ***rotor***.”

471. As discussed with respect to element [1D], the **rotor** comprises guide surfaces (i.e., “blades” having “leading edges” and “trailing edges.”) to produce centrifugal flow components.

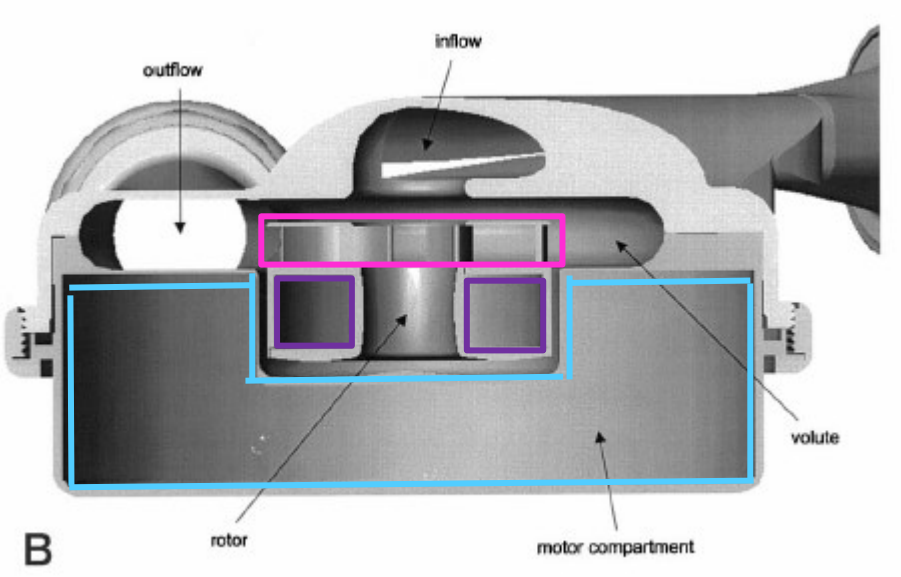
472. As discussed with respect to element [1H], Bourque-2001 discloses that the HeartMate III’s “rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely.” Ex.1007 at 401. The HeartMate III has a “lower housing” that includes “a cavity for the rotor” and “in which the motor is enclosed.” Ex.1007 at 401; *see also* Ex.1007 at 404 (“It was a fundamental goal of the HeartMate III mechanical design…to enclose a sophisticated motor.”), 402 (“installing the motors in the pump lower housings”).

473. In describing the blood flow path, Bourque-2001 discloses the “clearances above and below the rotor” which were “chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces.” Ex.1007

at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

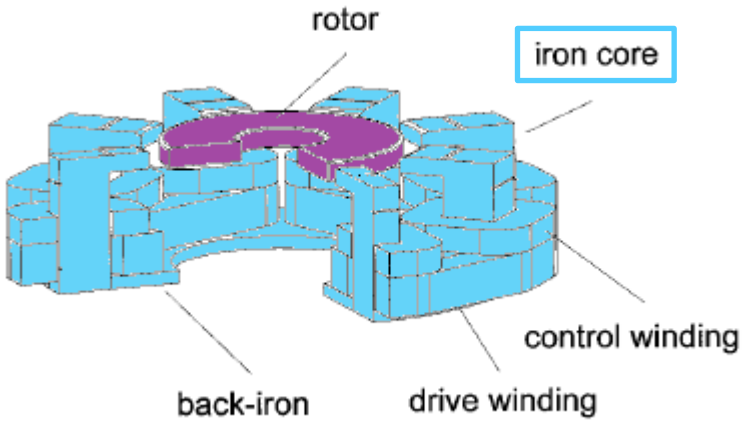
474. Figure 1B (annotated) illustrates that the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") is

spaced apart and sealed from the impeller of the rotor (**pink**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007 at Fig. 1B (annotated).

475. Figures 4 and 5 also illustrate the spacing between the "stator laminations" of the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007, Fig. 4.

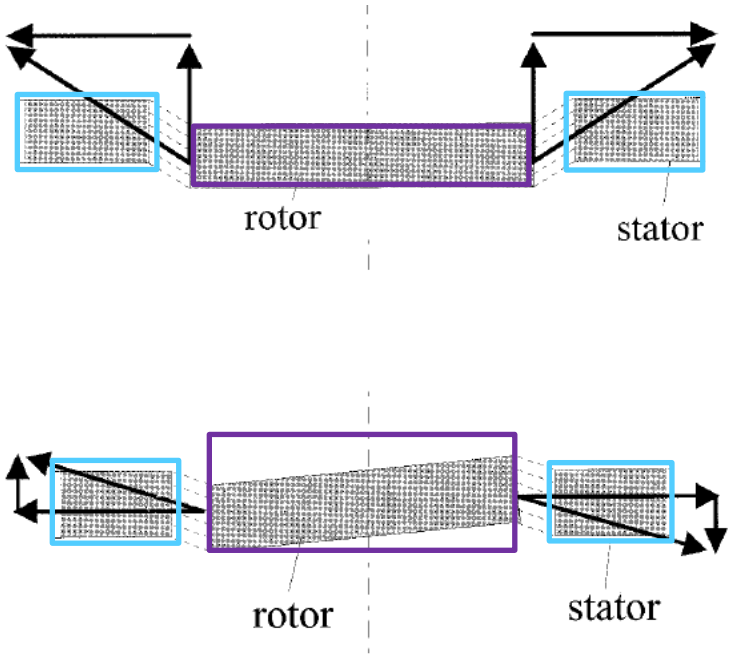


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

476. Accordingly, Bourque-2001 that "*the **second magnetic device*** ("motor") *being positioned axially spaced apart from the guide surfaces of the **rotor*** ("impeller")."

xi. [1J] a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly

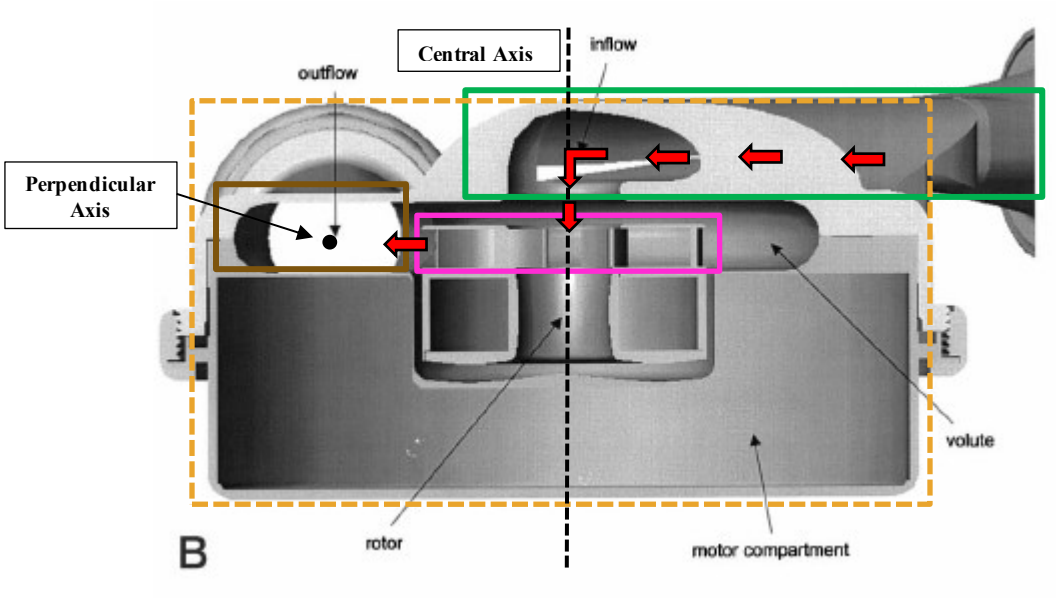
477. Bourque-2001 discloses "*a **blood outflow port** positioned radially adjacent the guide surfaces of the **rotor** such that, when the blood is driven by the **magnetically driven rotor assembly,** the blood exits the **surrounding stationary housing** in a direction substantially perpendicular to the **central axis** of the **magnetically driven rotor assembly***."

478. Bourque-2001 discloses that the HeartMate III includes an "outflow channel." Ex.1007 at 401. The "outflow channel" described in Bourque-2001 is a **blood outflow port** as recited in Claim 1. Bourque-2001 further describes that "[t]he **flow path is of circular cross-section** through the inflow and outflow sections…The flow exits the backswept blades of the impeller into a volute of uniformly increasing width, which terminates at a cutwater, peeling off most of the flow and directing it toward the outflow." Ex.1007 at 402. Thus, the **blood outflow**

port (e.g., "outflow channel") is "radially adjacent" to the guide surfaces of the **rotor** (e.g., the "impeller" of the rotor).

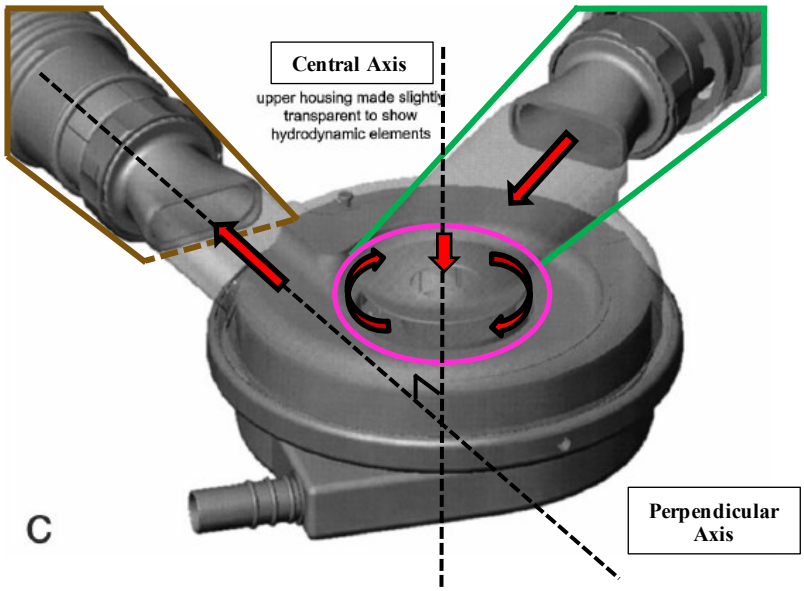
479. I note that in parallel litigation, the Patent Owner has asserted that the blood outflow port of the "HeartMate 3" is "radially adjacent" to a magnetically driven rotor in the same way as described above in Bourque-2001. *See* Ex.1019, at (Complaint, Ex. 13). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "outflow channel") is "radially adjacent" to the guide surfaces of the **rotor** (e.g., the "impeller" of the rotor) in the same way.

480. Figure 1B (annotated) illustrates that the outflow channel (**brown**) is radially adjacent to the guide surfaces of the impeller of the rotor (**pink**) such that blood is driven (**red** arrows) by the impeller to exit the upper and lower housing (**orange**) in a direction substantially perpendicular from the LV cannula of the inflow subassembly (**green**) and the central axis (**black**) of the impeller:



Ex.1007, Fig. 1B.

481. Similarly, Figure 1C (annotated) illustrates a view of the "flow paths" of blood (**red** arrows) through the HeartMate III in which blood is driven from the LV cannula of the inflow subassembly (**green**) by the impeller of the rotor (**pink**) to the outflow channel (**brown**) in a direction substantially perpendicular from the LV cannula of the inflow subassembly and the central axis (**black**):



Ex.1007, Fig. 1C (annotated).

482. Accordingly, Bourque-2001 discloses that "*a* ***blood outflow port*** ("outflow channel") *positioned radially adjacent the guide surfaces of the* ***rotor*** ("impeller") *such that, when the blood is driven by the* ***magnetically driven rotor assembly,*** *the blood exits the* ***surrounding stationary housing*** ("upper housing and lower housing") *in a direction substantially perpendicular to the* ***central axis*** *of the* ***magnetically driven rotor assembly***."

xii. [1K] wherein the magneto coupling is configured to both drive the rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and

483. Bourque-2001 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the magnetically driven rotor assembly such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **surrounding stationary housing** by the gap sized for passage of the blood*."

484. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the gap sized for passage of the blood**" to mean that the "blood flowing" "in response to rotation of the magnetically driven rotor" ***causes*** the "magnetically driven rotor" to remain "entirely spaced apart from the surrounding rotor housing." *See* Section VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "the

magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing by the blood flowing from the inflow tube and to the blood outflow port" to include not only hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

485. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [1G], Bourque-2001 discloses a magneto coupling between the **second magnetic device** (e.g., the "motor," Ex.1007 at 404) and the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, ***eliminating contact between moving parts*** and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

486. In addition, as discussed with respect to element [1F], in describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the

rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

487. Thus, the "magneto coupling" between the "passively magnetic elements" of the rotor and the "stator laminations" of the "motor" cause the rotor to be "magnetically suspended" such that, in response to rotation of the impeller of the rotor, the impeller remains entirely spaced apart from the surrounding rotor housing (e.g., "gaps permit up to 7× gravitational loads in any direction without contact ***between the rotor and housing***") for the passage of blood.

488. Accordingly, Bourque-2001 discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly***

("impeller" and "passively magnetic elements") *and orient the* ***magnetically driven rotor assembly*** *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***surrounding stationary housing*** ("upper housing and lower housing") *by the gap sized for passage of the blood*."

xiii. [1L] an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,

489. Bourque-2001 discloses "*an* ***external control unit*** *configured to regulate operation of the* ***second magnetic device*** *based upon a control value indicative of cardiac output*."

490. Bourque-2001 discloses connecting "electronics for power and control of the LVAD and for data acquisition" to the HeartMate III via an "electronic cable to be exteriorized percutaneously." Ex.1007 at 401, 403. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software" and that the "motor drive and control electronics" were external, because they had not been "incorporat[ed]…within the pump." Ex.1007 at 405. Accordingly, the "electronics for power and control" described in Bourque-2001 are an **external control unit** as recited in Claim 1.

491. The "electronics for power and control" (or "power driver") of the HeartMate III pump drive the motor by providing an electric current to the "stator laminations" of the "iron core" of the motor. Ex.1007 at 403, 404, Fig. 3, Fig. 4, Fig. 5. As discussed with respect to elements [1G] and [1K], the resulting magnetic field created by the "stators" of the motor causes the rotation and magnetic levitation of the "passively magnetic elements" of the rotor via a magneto coupling, and thereby drives the rotation of the "impeller" of the rotor. Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability."), 404, Figure 4; *see also supra* Sections X.B.1.viii and X.B.1.xii.

492. Figure 3 (annotated) illustrates the connection of the electronics for power and control (**lime green**) to the HeartMate III LVAD (**blue**):

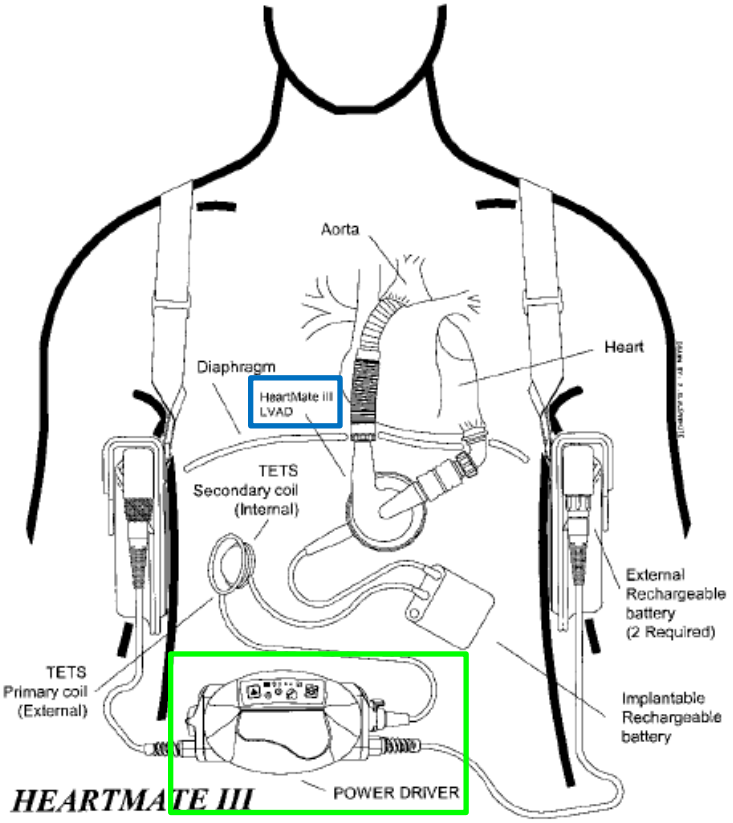


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

493. The 077 Patent does not define "a control value indicative of cardiac output." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 external control unit is configured to control the operation of the second magnetic device using a control value, such as what Abbott calls a "fixed speed" or "lower speed limit" which is indicative of cardiac output (e.g. output as measured in liters of blood per minute.

See, e.g., Ex.1019, Complaint, Ex. 13. For the purposes of my analysis, I adopt that construction of "measurement values indicative of cardiac output."

494. Accordingly, Bourque-2001 discloses Figure 7, which shows pressure head versus volume flow at various speeds:

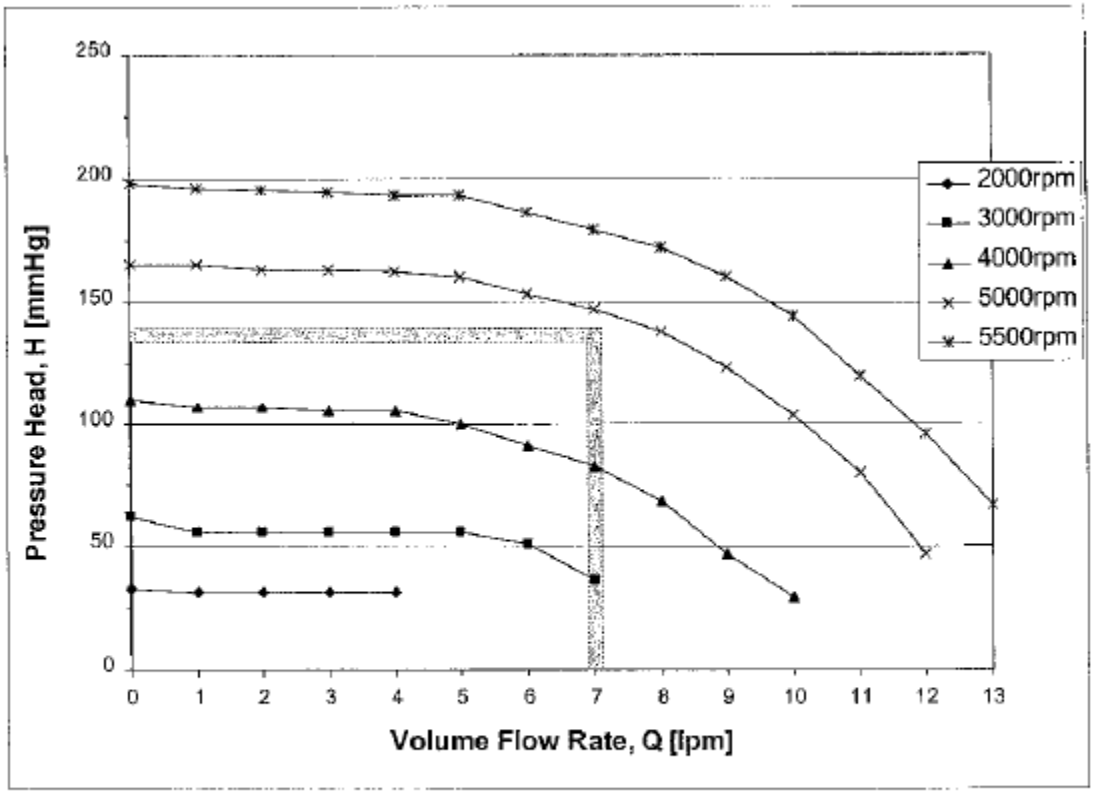


Figure 7. HeartMate III H-Q characteristic (the heavy, gray line indicates the design point).

495. Further, Bourque-2001 discloses that during testing, "[t]he animals were continuously monitored for general welfare, and certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and

blood chemistry (including plasma free hemoglobin) were periodically recorded. Ex.1007 at 403. In addition, during *in vitro* testing, "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." Ex.1007 at 403. Such parameters were "gradually adjusted to maintain volume flow rates" including at "desired maximum flow (10 L/min at 135 mm Hg)" and "prescribed to run at 3,500 rpm"). *Id.*; *see also id.* ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

496. Thus, the "electronics for power and control of the LVAD and for data acquisition" is an **external control unit** as recited in Claim 1 that controls the **second magnetic device** (e.g., the "motor," including the "stator laminations" and "windings," Ex.1007 at 404, Fig. 4) in response to measurement values indicative of cardiac output of the heart (e.g., "[s]peed and motor parameters were set and controlled" for example at "desired maximum flow (10 L/min at 135 mm Hg)," Ex.1007 at 403).

497. Accordingly, Bourque-2001 discloses "*an **external control unit*** ("electronics for power and control") *configured to regulate operation of the **second magnetic device*** ("motor") *based upon a control value indicative of cardiac output*."

xiv. [1M] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,

498. Bourque-2001 discloses that the "***external control unit*** *is connectable to the* ***heart assist pump device*** *for controlling the* ***second magnetic device*** *to thereby magnetically drive the rotation of the* ***magnetically driven rotor assembly*** *via the magneto coupling with the* ***first magnetic device***."

499. As discussed with respect to element [1L], the "electronics for power and control" described in Wampler-169 is an **external control unit** as recited in Claim 21 which regulates operation of the **second magnetic device** ("motor").

500. Bourque-2001 discloses connecting "electronics for power and control of the LVAD and for data acquisition" to the HeartMate III via an "electronic cable to be exteriorized percutaneously." Ex.1007 at 401, 403. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software" and that the "motor drive and control electronics" were external, because they had

not been "incorporat[ed]…within the pump." Ex.1007 at 405. Accordingly, the "electronics for power and control" described in Bourque-2001 are an **external control unit** as recited in Claim 1.

501. Bourque-2001 further discloses that during testing, "[t]he animals were continuously monitored for general welfare, and certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded. Ex.1007 at 403. In addition, during *in vitro* testing, "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." Ex.1007 at 403.

502. The "electronics for power and control" (or "power driver") of the HeartMate III pump drive the motor by providing an electric current to the "stator laminations" of the "iron core" of the motor. Ex.1007 at 403, 404, Fig. 3, Fig. 4, Fig. 5. As discussed with respect to elements [1J] and [1M], the resulting magnetic field created by the "stators" of the motor causes the rotation and magnetic levitation of the "passively magnetic elements" of the rotor via a magneto coupling, and thereby drives the rotation of the "impeller" of the rotor. Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency.

Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability."), 404, Figure 4; *see also supra* Sections X.B.1.xi and X.B.1.xiv.

503. Figure 3 (annotated) illustrates the connection of the electronics for power and control (**lime green**) to the HeartMate III LVAD (**blue**):

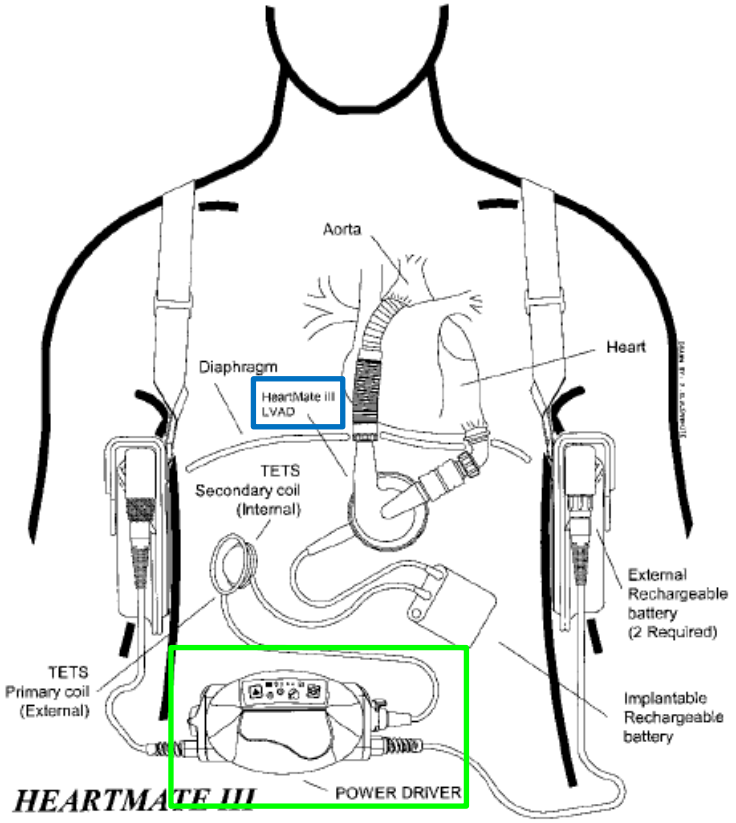


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

504. Accordingly, Bourque-2001 discloses that the "***external control unit*** ("electronics for power and control") *is connectable to the* ***heart assist pump device*** ("HeartMate III LVAD") *for controlling the* ***second magnetic device*** ("motor") *to thereby magnetically drive the rotation of the* ***magnetically driven rotor assembly*** ("impeller") *via the magneto coupling with the* ***first magnetic device*** ("passively magnetic elements")."

505. Based on my analysis, Bourque-2001 discloses and/or renders obvious each and every element of Claim 1 of the 077 Patent.

2. Claims 2, 3, and 4

506. Claim 4 depends from dependent claim 3 which depends from dependent Claim 2 which depends from independent Claim 1. Accordingly, I address each dependent claim in turn.

a. [2] The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.

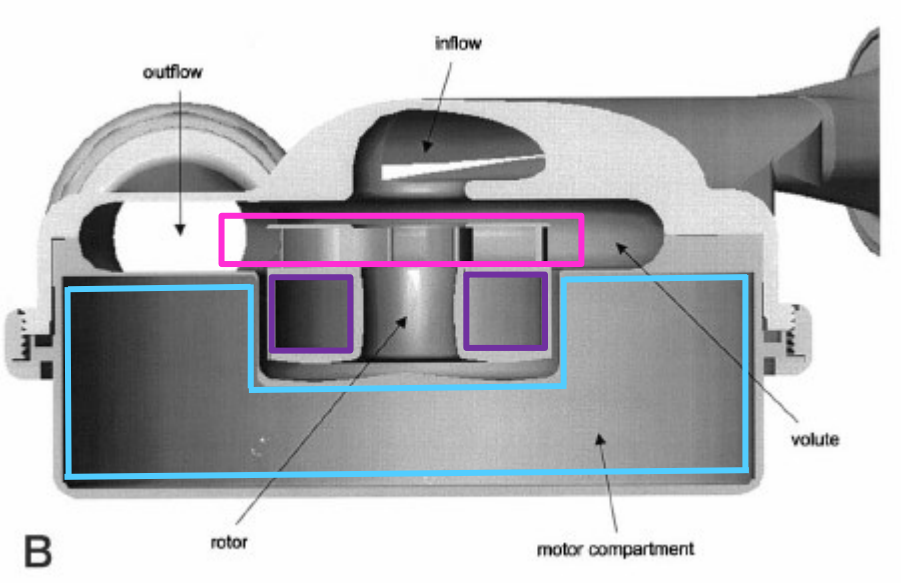
507. Bourque-2001 discloses and/or renders obvious claim 2. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 2.

508. Bourque-2001 discloses that "*the **first magnetic device** is configured to be positioned between the **second magnetic device** and the guide surfaces of the **rotor** of the **magnetically driven rotor assembly***."

509. As discussed with respect to element [1G], the **second magnetic device** (e.g., the "motor," including the "stator laminations" and "windings," Ex.1007 at 404, Fig. 4) drives rotation of the **magnetically driven rotor** (e.g., the "impeller" of the rotor, Ex.1007 at 401) via a magneto coupling with the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). *See supra* Section X.B.1.viii. For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

510. Thus, the "passive magnetic elements" of the rotor are necessarily between the "motor" and the "impeller" in order for the motor to drive the impeller's motion. Figure 1B (annotated) illustrates that the passively magnetic elements of the rotor (**purple**) are positioned between the motor (**light blue**, not shown but Bourque-

2001 describes the "motor is enclosed" in the "lower housing") and the impeller of the rotor (**pink**):



Ex.1007 at Fig. 1B (annotated).

511. Accordingly, Bourque-2001 discloses that "*the **first magnetic device*** ("passively magnetic elements") *is configured to be positioned between the **second magnetic device*** ("motor") *and the guide surfaces of the **rotor*** ("impeller") *of the **magnetically driven rotor assembly***."

b. [3] The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.

512. Bourque-2001 discloses and/or renders obvious claim 3. I have already explained how Bourque-2001 discloses and/or renders obvious each and every

element of claims 1 and 2. I incorporate that discussion into my analysis for claim 3.

513. Bourque-2001 discloses that "*the **first magnetic device** is configured to rotate together with the **rotor** relative to the **surrounding stationary housing***."

514. As discussed with respect to element [1C], the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) is rigidly coupled to the **magnetically driven rotor** (e.g., the "impeller" of the rotor). *See supra* Section X.B.1.iv. And as discussed with respect to element [1G], Bourque-2001 further discloses how the motor impacts the rate of blood flow produced by the **magnetically driven rotor** (e.g., the "impeller" of the rotor), confirming that the **second magnetic device** (e.g., "motor") of the HeartMate III is positioned to magnetically drive rotation of the **magnetically driven rotor** via the electromagnetic field applied to the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor). Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability."); *See supra* Section X.B.1.viii.

515. For the same reasons, because the "passively magnetic elements" of the rotor are rigidly coupled to the "impeller," the "passively magnetic elements" rotate together with the "impeller" of the rotor relative to and within the housing.

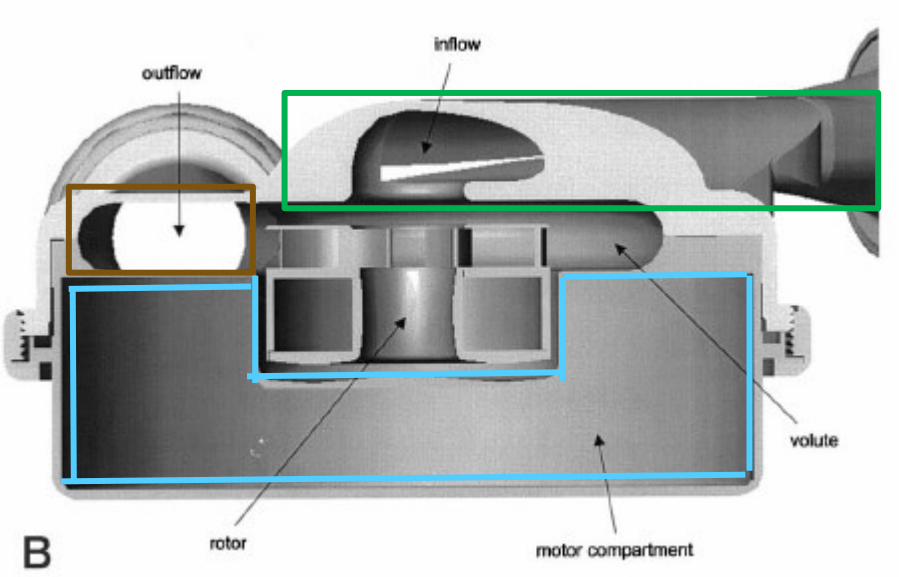
516. Accordingly, Bourque-2001 discloses that "*the **first magnetic device*** ("passively magnetic elements") *is configured to rotate together with the **rotor*** ("impeller") *relative to the **surrounding stationary housing*** ("upper housing and lower housing")."

c. [4] The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.

517. Bourque-2001 discloses and/or renders obvious claim $. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claims 1, 2, and 3. I incorporate that discussion into my analysis for claim 4.

518. Bourque-2001 discloses that "*the **second magnetic device** is positioned closer to the **blood outflow port** than to the suction end of the **inflow tube**.*"

519. For example, Figure 1B (annotated) illustrates that the motor (**light blue**) is positioned closer to the outflow channel (**brown**) than the motor is positioned relative to the suction end of the left ventricular (LV) cannula (**green**):



Ex.1007 at Fig. 1B (annotated).

520. I note that to the extent Bourque-2001 would be modified to remove the elbow in the inflow subassembly including the left ventricular (LV) cannula, the motor would still be positioned closer to the outflow channel than to the suction end of the left ventricular (LV) cannula.

521. Accordingly, Bourque-2001 discloses that "*the **second magnetic device*** ("motor") *is positioned closer to the **blood outflow port*** ("outflow channel") *than to the suction end of the **inflow tube*** ("an inflow subassembly that includes a left ventricular (LV) cannula")."

3. Claim 5

a. [5] The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.

522. Bourque-2001 discloses claim 5. I have already explained how Bourque-2001 discloses each and every element of claim 1. I incorporate that discussion into my analysis for claim 5.

523. Bourque-2001 discloses that "*the **magnetically driven rotor assembly** is sealed from the **second magnetic device** and a drive source configured to regulate the operation of the **second magnetic device**.*"

524. As discussed with respect to [1H], the **impeller** and **passively magnetic elements** are sealed from the **motor**.

525. Further, as discussed with respect to elements [1L] and [1M], Bourque-2001 discloses connecting "electronics for power and control of the LVAD and for data acquisition" to the HeartMate III via an "electronic cable to be exteriorized percutaneously." Ex.1007 at 401, 403. Ex.1006 at 3, 4. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software" and that the "motor drive and control electronics" were external, because they had not been "incorporat[ed]…within the pump." Ex.1007 at 405.

526. Accordingly, Bourque-2001 discloses that "*the **magnetically driven rotor assembly*** ("impeller") *is sealed from the **second magnetic device*** ("motor") *and a drive source configured to regulate the operation of the **second magnetic device***."

4. Claim 7

a. [7] The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

527. Bourque-2001 discloses and/or renders obvious claim 7. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 7.

528. Bourque-2001 discloses "*one or more sensors configured to deliver feedback signals to the **external control unit***."

529. For example, Bourque-2001 discloses that the "electronics for power and control of the LVAD and for data acquisition resided on a shelf." Ex.1007 at 403. Bourque-2001 further discloses that "[s]peed and motor parameters were set and controlled using software specifically designed to develop the HeartMate III." A POSITA would have understood based on the disclosure of this setup that these speed and motor parameters were monitored by a sensor providing feedback to the controller.

530. In addition, during testing, "flow measurements were made with an ultrasonic flow probe,…and pressure measurements were made with solid-state catheter-type pressure transducers." Ex.1007 at 403. "All measurements were automatically processed and recorded using Labview." Ex.1007 at 403. An "ultrasonic flow probe" is a device that measures the flow rate of a fluid, and a "solid-state catheter-type pressure transducer" measures pressure by converting pressure into electrical signals. Each of these devices was well known at the time of the purported invention on February 27, 2007. Each of the "ultrasonic flow probe" and the "solid-state catheter-type pressure transducer" described in Bourque-2001 is a "sensor" as recited in Claim 7 that provides feedback signals to the **external control unit** (e.g., "electronics for power and control" and "data acquisition").

531. These are the same type of "measurement signals" discussed in the 077 Patent's specification. Ex.1001, 3:11-16 ("The catheter is introduced here for example via the femoral artery and the aortic arch 3 into the heart chamber and carries ***a series of sensors 4 via which the volume can be determined***. The measurement signals are passed to a control arrangement 5."), 3:34-39 ("The volumetric measurement in the cardiac chamber allows differences to be reliably detected between the diastolic and systolic volume and allows corresponding

correction signals to be made available for the output of the synchronised fluid pump 7.").

532. Accordingly, Bourque-2001 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit*** ("electronics for power and control")."

5. Claim 10

a. [10] The system of claim 1, wherein the heart assist pump device is a catheter device.

533. Bourque-2001 discloses and/or renders obvious claim 10. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 10.

534. Bourque-2001 discloses that "*the* ***heart assist pump device*** *is a catheter device*."

535. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See, e.g.*, Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "catheter device."

536. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], the HeartMate III disclosed in Bourque-2001 includes a "catheter" which is an **inflow tube** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) that has a suction end that is delivered to the left ventricle of the heart "via left ventricular apical cannulation." Ex.1007 at 401, 403, Fig. 4. Therefore, the HeartMate III pump disclosed in Bourque-2001 is a catheter device.

537. Accordingly, Bourque-2001 discloses that "*the **heart assist pump device*** ("HeartMate III LVAD") *is a catheter device*."

6. Claim 16

538. As demonstrated below, the scope of claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. For instance, the "surrounding stationary housing" of claim 1 is essentially the same as the "chamber walls at least partially defining a chamber" of claim 16. Similarly, because the "inflow tube" and "central axis" of claim 1 are aligned, the claimed "inflow axis" of claim 16 is rendered obvious for the same reasons.

a. [16pre] A system for assisting blood circulation of a heart, the system comprising

539. Bourque-2001 discloses "*a system for assisting blood circulation of a **heart***."

540. This element is invalid for the same reasons discussed above in [1PRE], thus, I incorporate that discussion into my analysis here.

541. Accordingly, Bourque-2001 discloses "a system for assisting blood circulation of a **heart**."

b. [16a] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;

542. Bourque-2001 discloses "*a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**.*"

543. This element is invalid for the same reasons discussed above in [1A] and [1B], thus, I incorporate that discussion into my analysis here.

544. Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, discloses "a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**."

c. [16b] chamber walls at least partially defining a chamber to receive blood from the inflow tube;

545. Bourque-2001 discloses "***chamber walls at least partially defining a chamber** to receive blood from the **inflow tube**.*"

546. This element is invalid for the same reasons discussed above in [1E] and [1F], thus, I incorporate that discussion into my analysis here.

547. Accordingly, Bourque-2001 discloses "***chamber walls at least partially defining a chamber*** *to receive blood from the* ***inflow tube***."

d. [16c] a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device

548. Bourque-2001 discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

549. This element is invalid for the same reasons discussed above in [1B] and [1C], thus, I incorporate that discussion into my analysis here.

550. Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

e. [16d] that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor

551. Bourque-2001 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

552. This element is invalid for the same reasons discussed above in [1C], thus, I incorporate that discussion into my analysis here.

553. Accordingly, Bourque-2001 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

f. [16e] [the rotor] having guide surfaces to produce centrifugal flow components,

554. Bourque-2001 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

555. This element is invalid for the same reasons discussed above in [1D], thus, I incorporate that discussion into my analysis here.

556. Accordingly, Bourque-2001 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

g. [16f] the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation

557. Bourque-2001 discloses "*the* ***rotor*** *and the* ***first magnetic device*** *of the* ***magnetically driven rotor assembly*** *being rotatable within the* ***chamber*** *about an axis of rotation*."

558. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

559. Accordingly, Bourque-2001 discloses "*the* ***rotor*** *and the* ***first magnetic device*** *of the* ***magnetically driven rotor assembly*** *being rotatable within the* ***chamber*** *about an axis of rotation*."

h. [16g] [the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;

560. Bourque-2001 discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

561. This element is invalid for the same reasons discussed above in [1B] and [1E], thus, I incorporate that discussion into my analysis here.

562. Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

i. [16h] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

563. Bourque-2001 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

564. This element is invalid for the same reasons discussed above in [1G], thus, I incorporate that discussion into my analysis here. Additionally, Bourque-2001 refers to the "motor" ("***magnetic drive system***") as "includ[ing] drive and levitation in a single magnetic structure as shown in Figure 4," and thus, Bourque-2001 discloses a "*magnetic drive system*." Ex.1007, 402.

565. Accordingly, Bourque-2001, or Bourque-2001/Wampler-169, discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

j. [16i] the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and

566. Bourque-2001 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device***."

567. This element is invalid for the same reasons discussed above in [1K] and [2], thus, I incorporate that discussion into my analysis here.

568. Accordingly, Bourque-2001 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device***."

k. [16j] and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,

569. Bourque-2001 discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

570. This element is invalid for the same reasons discussed above in [1H], thus, I incorporate that discussion into my analysis here.

571. Accordingly, Bourque-2001 discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

l. [16k] a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,

572. Bourque-2001 discloses "*a **blood outflow port** positioned radially outward of the guide surfaces of the **rotor** such that, when the blood is driven by*

*the **magnetically driven rotor assembly**, the blood exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

573. This element is invalid for the same reasons discussed above in [1J], thus, I incorporate that discussion into my analysis here.

574. Accordingly, Bourque-2001 discloses "*a **blood outflow port** positioned radially outward of the guide surfaces of the **rotor** such that, when the blood is driven by the **magnetically driven rotor assembly**, the blood exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

m. [16l] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and

575. Bourque-2001 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

576. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

577. Accordingly, Bourque-2001 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

n. [16m] an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output

578. Bourque-2001 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

579. This element is invalid for the same reasons discussed above in [1L], thus, I incorporate that discussion into my analysis here.

580. Accordingly, Bourque-2001 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

o. [16n] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

581. Bourque-2001 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

582. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

583. Accordingly, Bourque-2001 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

7. Claim 17

a. [17] The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.

584. Bourque-2001 discloses and/or renders obvious claim 17. I have already explained how Bourque-2001 discloses and/or renders obvious each and

every element of claim 16. I incorporate that discussion into my analysis for claim 17.

585. Bourque-2001 discloses that "*the **first magnetic device** is rigidly coupled to the **rotor** of the **magnetically driven rotor assembly** at a position between the **second magnetic device** and the **rotor**.*"

586. This element is invalid for the same reasons discussed above in [2], [16D], and [16I], thus, I incorporate that discussion into my analysis here.

587. Accordingly, Bourque-2001 discloses that "*the **first magnetic device*** ("passively magnetic elements") *is rigidly coupled to the **rotor*** ("impeller") *of the **magnetically driven rotor assembly** at a position between the **second magnetic device*** ("motor") *and the **rotor**.*"

8. Claims 18, 19, 20, and 21

588. Claim 21 depends from dependent claim 19 which depends from dependent Claim 18 which depends from independent claim 16. Accordingly, I address each dependent claim in turn.

a. [18] The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.

589. Bourque-2001 discloses and/or renders obvious claim 18. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 18.

590. Bourque-2001 discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the* ***second magnetic device*** *drives the rotation of the* ***magnetically driven rotor assembly***."

591. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "**gap sized for passage of the blood** is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly" to mean that the "blood flowing" "when the second magnetic device drives the rotation of the magnetically driven rotor assembly" ***causes*** the "gap sized for passage of the blood." *See* Section VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "by a gap sized for passage of the blood" to include not only

hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

592. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [1G], Bourque-2001 discloses a magneto coupling between the **second magnetic device** (e.g., the "motor," Ex.1007 at 404) and the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, ***eliminating contact between moving parts*** and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

593. In addition, as discussed with respect to element [1C], the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401) is rigidly coupled to the **magnetically driven rotor assembly** (e.g., the "impeller" of the rotor). Bourque-2001 further discloses how the motor impacts the rate of blood flow produced by the **magnetically driven rotor assembly** (e.g., the "impeller" of the rotor), confirming that the **second magnetic device** (e.g., "motor") of the HeartMate III is positioned to magnetically drive rotation of the **magnetically**

driven rotor assembly via the electromagnetic field applied to the **first magnetic device** (e.g., the "passively magnetic elements" of the rotor). Ex.1007 at 403 ("Note that the design point (7 L/min at 135 mm Hg) occurs between 4,500 rpm and 5,000 rpm, which happens to be near the optimal speed for maximum motor efficiency. Furthermore, the desired maximum flow (10 L/min at 135 mm Hg) is achieved below 5,500 rpm, also at high efficiency and well below the motor's maximum capability.").

594. In describing the blood flow path, Bourque-2001 further discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively

controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

595. Thus, the "magneto coupling" between the "passively magnetic elements" of the rotor and the "stator laminations" of the "motor" cause the rotor to be "magnetically suspended" such that, in response to rotation of the impeller of the rotor, the impeller remains entirely spaced apart from the surrounding rotor housing (e.g., "gaps permit up to 7× gravitational loads in any direction without contact ***between the rotor and housing***").

596. Accordingly, Bourque-2001 discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor assembly*** ("impeller")."

b. [19] The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.

597. Bourque-2001 discloses claim 19. I have already explained how Bourque-2001 discloses each and every element of claim 18. I incorporate that discussion into my analysis for claim 19.

598. Bourque-2001 discloses that "*the gap surrounds the **magnetically driven rotor assembly***."

599. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

600. Accordingly, Bourque-2001 discloses that "*the gap surrounds the **magnetically driven rotor assembly***."

c. [20] The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.

601. Bourque-2001 discloses claim 20. I have already explained how Bourque-2001 discloses each and every element of claims 18 and 19. I incorporate that discussion into my analysis for claim 20.

602. Bourque-2001 discloses that "*at least part of the gap extends radially outward from the **magnetically driven rotor assembly***."

603. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

604. Accordingly, Bourque-2001 discloses that "*at least part of the gap extends radially outward from the **magnetically driven rotor assembly***."

d. [21] The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.

605. Bourque-2001 discloses claim 21. I have already explained how Bourque-2001 discloses each and every element of claims 18, 19, and 20. I incorporate that discussion into my analysis for claim 21.

606. Bourque-2001 discloses that "*at least part of the gap extends along a face of the* ***magnetically driven rotor assembly*** *that is axially opposite from the* ***inflow tube***."

607. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the* ***magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

608. Accordingly, Bourque-2001 discloses that "*at least part of the gap extends along a face of the* ***magnetically driven rotor assembly*** *that is axially opposite from the* ***inflow tube***."

9. Claims 22 and 23

609. Claim 23, depends from dependent Claim 22 which depends from independent Claim 16. Accordingly, I address each dependent claim in turn.

a. [22] The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

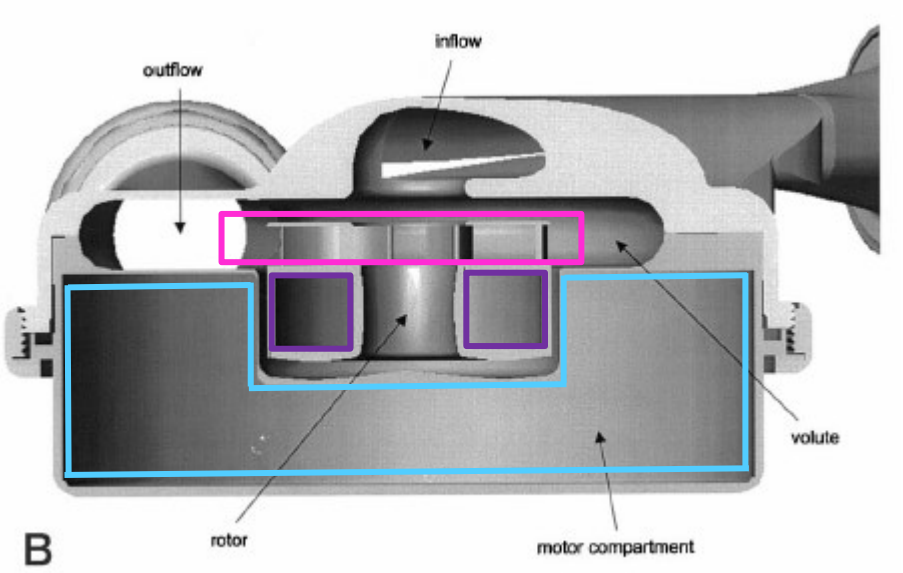
610. Bourque-2001 discloses and/or renders obvious claim 22. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 22.

611. Bourque-2001 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly** is positioned, and the magnetic drive system is positioned within a **second chamber** sealed from the **first chamber**.*"

612. As discussed with respect to element [1G], the **second magnetic device** (e.g., the "motor," including the "stator laminations" and "windings," Ex.1007 at 404, Fig. 4) drives rotation of the **magnetically driven rotor assembly** (e.g., the "impeller" of the rotor, Ex.1007 at 401) via a magneto coupling with the **first chamber** (e.g., the "passively magnetic elements" of the rotor, Ex.1007 at 401). *See supra* Section X.B.1.viii. For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and consequently extending wear life indefinitely." Ex.1007 at 401. "The rotor is passively magnetically levitated in the axial-translational and transverse-rotational

degrees of freedom (Figure 5) and actively magnetically levitated in the remaining degrees of freedom." Ex.1007 at 402-403.

613. Thus, the "passive magnetic elements" of the rotor are necessarily between the "motor" and the "impeller" in order for the motor to drive the impeller's motion. Figure 1B (annotated) illustrates that the passively magnetic elements of the rotor (**purple**) are positioned between the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") and the impeller of the rotor (**pink**):



Ex.1007 at Fig. 1B (annotated).

614. For example, Bourque-2001 discloses that the HeartMate III's "rotor is magnetically suspended, eliminating contact between moving parts and

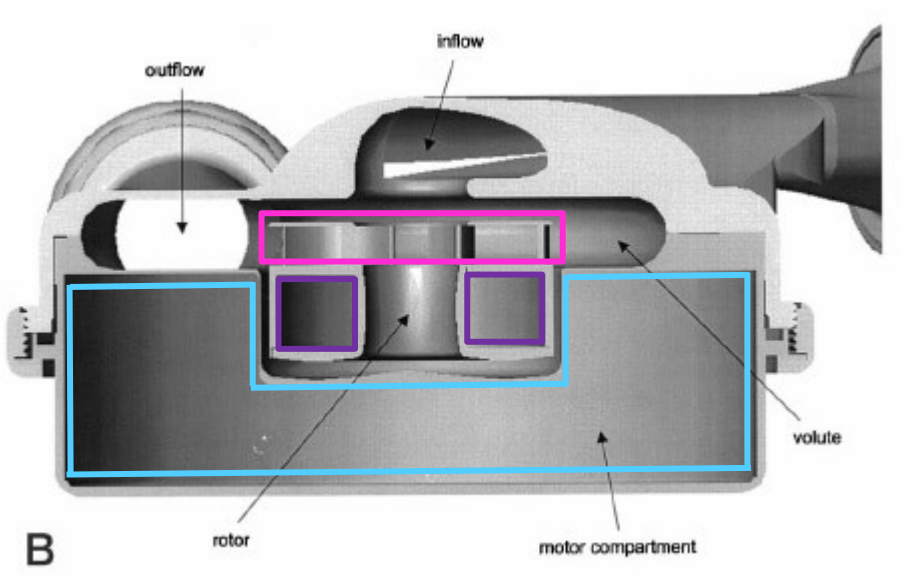
consequently extending wear life indefinitely." Ex.1007 at 401. The HeartMate III has a "lower housing" that includes "a cavity for the rotor" and "in which the motor is enclosed." Ex.1007 at 401; *see also* Ex.1007 at 404 ("It was a fundamental goal of the HeartMate III mechanical design…to enclose a sophisticated motor."), 402 ("installing the motors in the pump lower housings").

615. Bourque-2001 further discloses that the **second chamber** (e.g., the "motor") is sealed by "titanium surfaces…textured in the same way as the HeartMate and HeartMate II,…intended to promote the development of a stable, adherent pseudoneointima immediately upon contact with blood, thereby insulating subsequent blood flow from contact with nonbiologic materials and reducing the risk of thromboembolism." Bourque-2001 at 401 (citations omitted).

616. In describing the blood flow path, Bourque-2001 discloses the "clearances above and below the rotor" which were "chosen to balance reduced hydraulic efficiency with sufficient washing of blood contacting surfaces." Ex.1007 at 402; *see also* Ex.1007 at 402 ("An opening in the shroud (i.e., the cover across the top of the blades on the rotor) permits fluid leaving the inflow conduit to enter the impeller. This results in a backflow path from the trailing edges of the blades (where the pressure is relatively high), over the shroud, and back to the leading edges of the blades. By creating a similar opening in the lower half of the rotor, a second

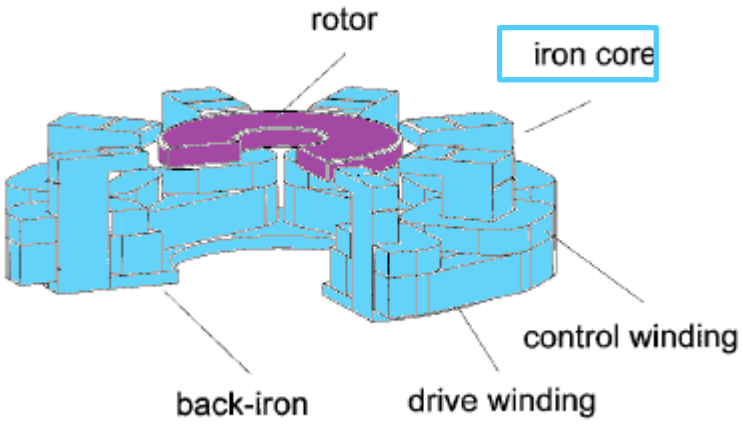
backflow path underneath the rotor results, eliminating what would have been an accumulation of stagnant blood there, and relieving the upward thrust load on the rotor."); *see also* Ex.1007 at 402 (Backflow clearances were further constrained by the stiffness of the magnetic suspension (passive in the axial direction, actively controlled in the radial direction), which describes the levitation system's capacity to counteract imposed deviations of rotor position; the gaps permit up to 7× gravitational loads in any direction without contact between the rotor and housing.").

617. Figure 1B (annotated) illustrates that the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") is spaced apart and sealed from the impeller of the rotor (**pink**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007 at Fig. 1B (annotated).

618. Figures 4 and 5 also illustrate the spacing and sealing between the "stator laminations" of the motor (**light blue**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007, Fig. 4.

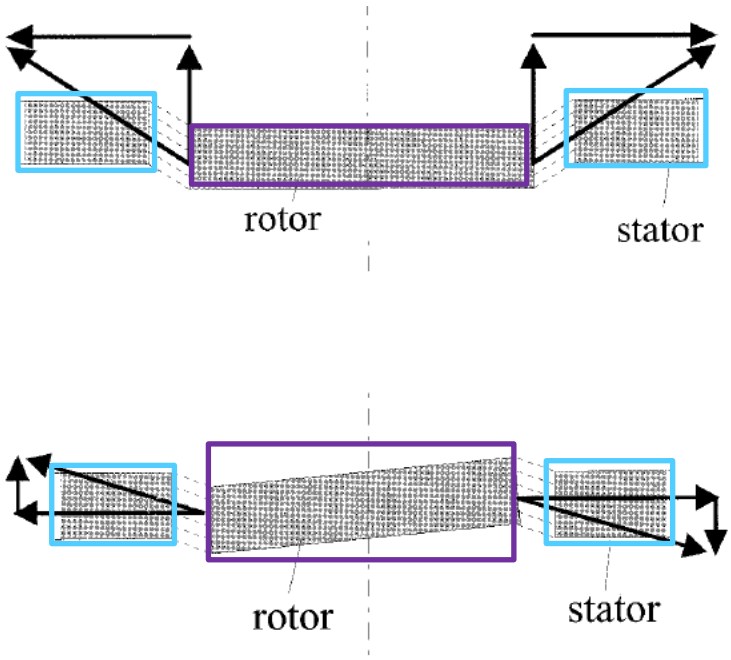


Figure 5. Passive magnetic levitation. Above, Restoration force when axially displaced. Below, Restoration force when tilted.

Ex.1007, Fig. 5.

619. Accordingly, Bourque-2001 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly*** ("impeller") *is positioned, and the magnetic drive system is positioned within a **second chamber*** ("motor") *sealed from the **first chamber*** ("passively magnetic elements")."

b. [23] The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.

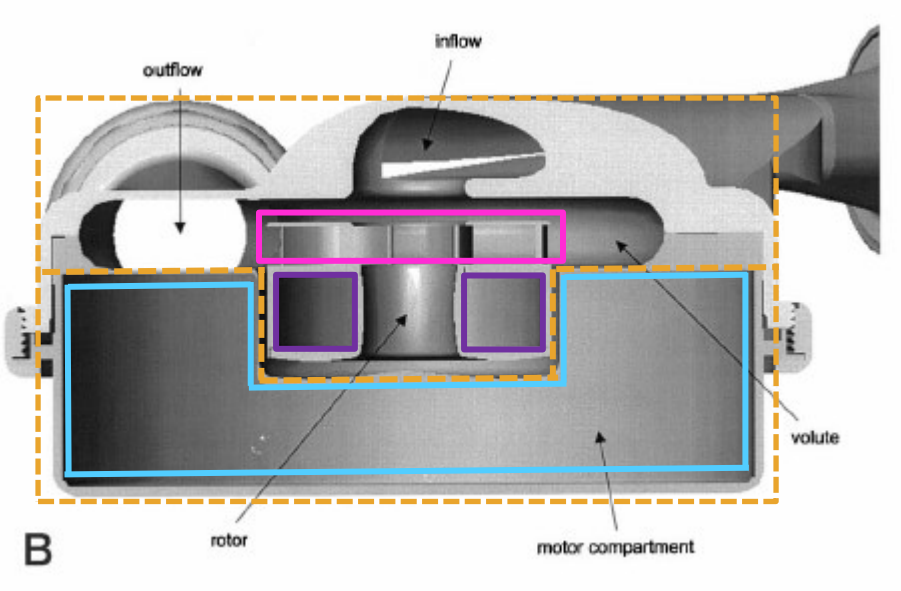
620. Bourque-2001 discloses and/or renders obvious claim 23. I have already explained how Bourque-2001 discloses and/or renders obvious each and

every element of claim 22. I incorporate that discussion into my analysis for claim 23.

621. Bourque-2001 discloses that a "*wall of the chamber walls separates the **first chamber** from the **second chamber***." As discussed with respect to element [1E], Bourque discloses that the magnetically driven rotor is rotatable within **a surrounding rotor housing** (e.g., the "lower housing" and "upper housing" when clamped together by the "screw ring") of the HeartMate III pump to act upon blood flowing from the **inflow tube** (e.g., "an inflow subassembly that includes a left ventricular (LV) cannula," Ex.1007 at 401) toward the **magnetically driven rotor** (e.g., "impeller" of the rotor).

622. Bourque-2001 further discloses that the "lower housing" of the HeartMate III pump includes "a cavity for the rotor" and is where "the motor is enclosed." Ex.1007 at 401. Further, the "backflow clearance" gaps created by the flow of blood through the impeller "permit up to 7× gravitational loads in any direction ***without contact between the rotor and the housing***." Thus, the "cavity for the rotor," which includes the "passively magnetic elements," creates a sealing wall between the **second magnetic device** (e.g., the "motor") and the **first chamber** (e.g., the "passively magnetic elements" of the rotor) to eliminate contact. Ex.1007 at 401-402.

623. Figure 1B (annotated) illustrates that a sealing wall (i.e., the cavity for the rotor) in the housing (**orange**) separates the motor (**light blue**, not shown but Bourque-2001 describes the "motor is enclosed" in the "lower housing") from the impeller of the rotor (**pink**) and the passively magnetic elements of the rotor (**purple**):



Ex.1007 at Fig. 1B (annotated).

624. Accordingly, Bourque-2001 discloses that a "*wall of the chamber walls separates the **first chamber*** ("passively magnetic elements") *from the **second chamber*** ("motor")."

10. Claim 24

a. [24] The system of claim 16, wherein the first magnetic device comprises a permanent magnet.

625. Bourque-2001 discloses claim 24. I have already explained how Bourque-2001 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 24.

626. Bourque-2001 discloses that "*the **first magnetic device** comprises a permanent magnet*."

627. This element is invalid for the same reasons discussed above in [1C] and [16C], thus, I incorporate that discussion into my analysis here.

628. Accordingly, Bourque-2001 discloses that "*the **first magnetic device** comprises a permanent magnet*."

11. Claim 26

a. [26] The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

629. Bourque-2001 discloses and/or renders obvious claim 26. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 26.

630. Bourque-2001 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit***."

631. This element is invalid for the same reasons discussed above in [7], thus, I incorporate that discussion into my analysis here.

632. Accordingly, Bourque-2001 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit*** ("electronics for power and control")."

12. Claim 28

a. [28] The system of claim 16, wherein the heart assist pump device is a catheter device.

633. Bourque-2001 discloses and/or renders obvious claim 28. I have already explained how Bourque-2001 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 28.

634. Bourque-2001 discloses that "*the* ***heart assist pump device*** *is a catheter device*."

635. This element is invalid for the same reasons discussed above in [10], thus, I incorporate that discussion into my analysis here.

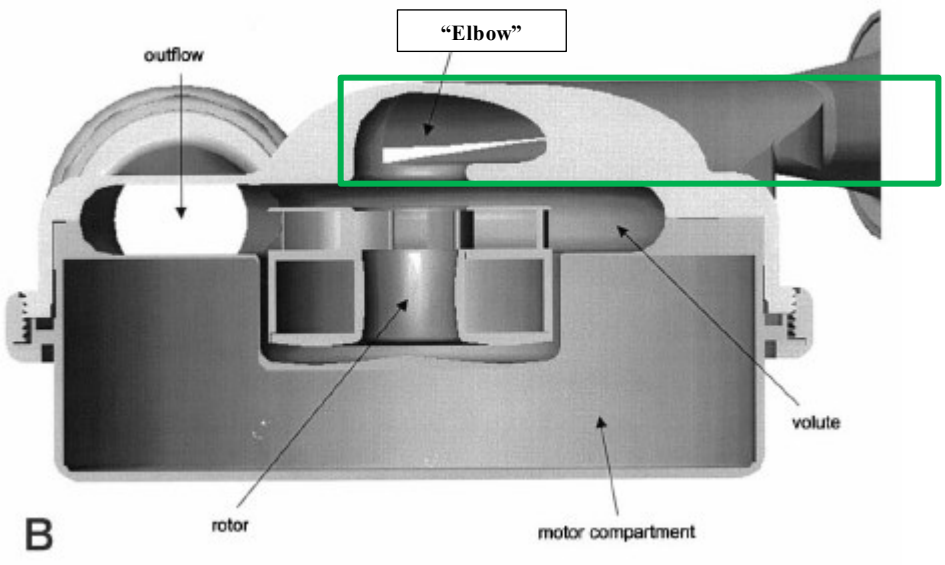
636. Accordingly, Bourque-2001 discloses that "*the* ***heart assist pump device*** ("HeartMate III LVAD") *is a catheter device*."

13. Motivation to Combine Bourque-2001 with Wampler-169

637. It would have been obvious to include Wampler's techniques related to use of an *axially aligned inflow tube* in the Bourque-2001 device for the reasons explained below.

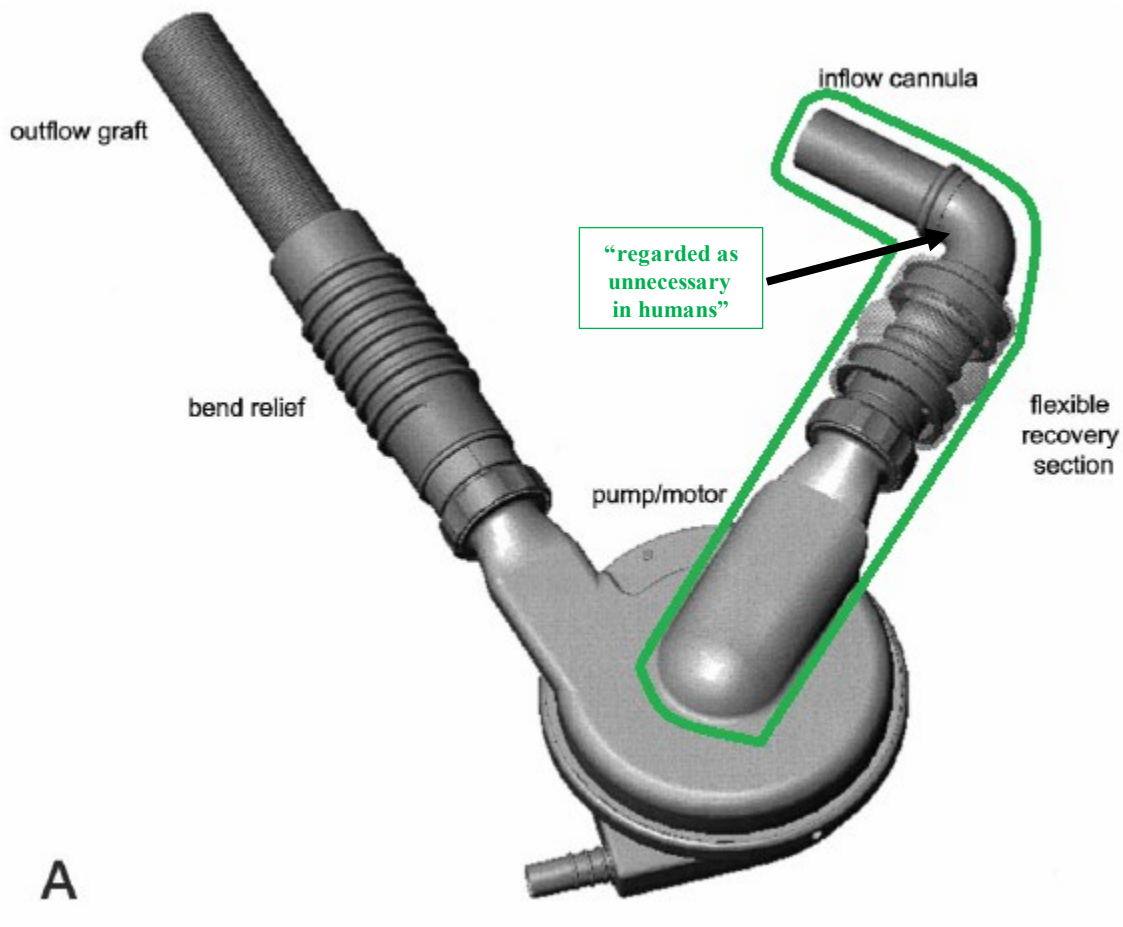
638. As discussed above, the Bourque-2001 device is "a centrifugal pump," and by definition of it being a centrifugal pump, the Bourque-2001 device already comprises an *axially aligned inflow tube.* By design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference.

639. The HeartMate III's ***inflow tube*** ("inflow subassembly that includes a left ventricular (LV) cannula"), however, also comprises an "elbow," as shown:



Ex.1007 at Fig. 1B (annotated).

640. Bourque-2001 describes that HeartMate III's ***inflow tube*** comprised another "elbow in the inflow segment, included to accommodate the bovine anatomy and presently regarded as unnecessary in humans," shown below in Figure 1A (annotated):



Ex.1007, Fig. 1A.

641. The HeartMate III's ***inflow tube*** is also illustrated in Figure 3 (annotated):

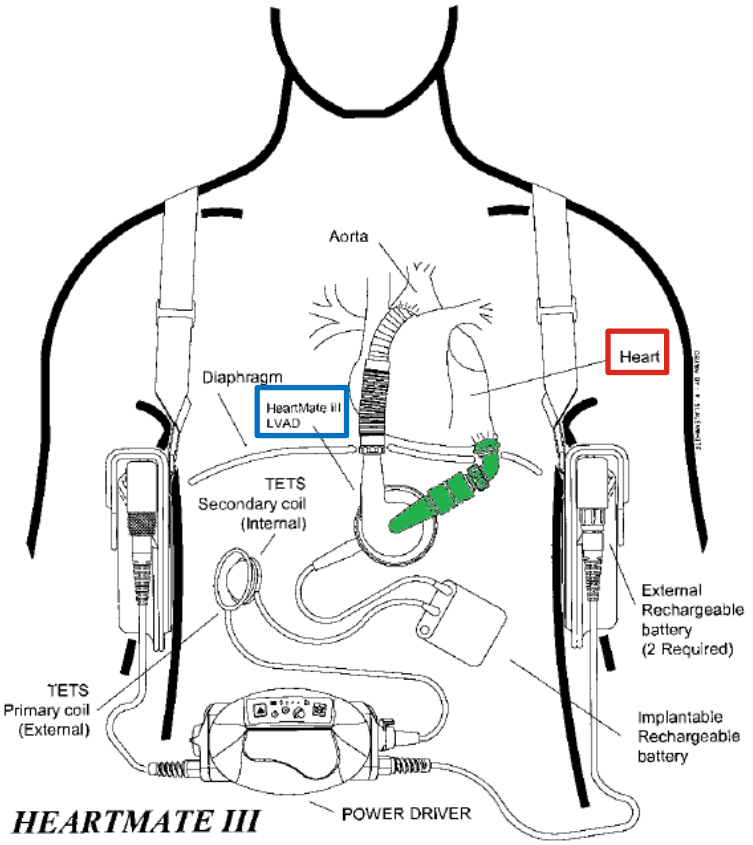
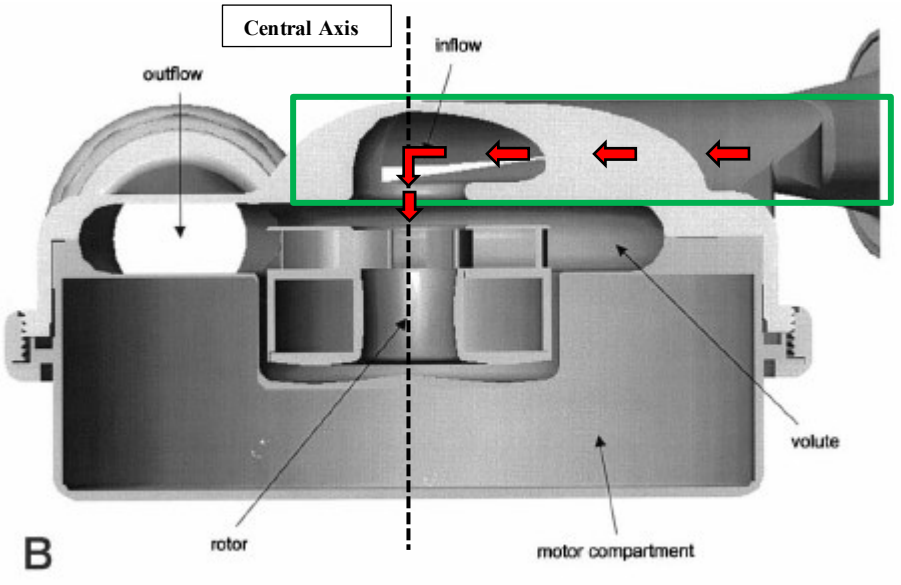


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3 (annotated).

642. The elbow ("sharp bend in the flow before it enters the impeller") was included in the Bourque-2001 device because "the rotational axis of the pump's rotor [is] perpendicular to the body's long axis" which "resulted in a sharp bend in the flow before it enters the impeller." Ex.1007 at 402. Figure 1B (annotated) below illustrates the inflow subassembly (**green**) of the Bourque-2001 HeartMate

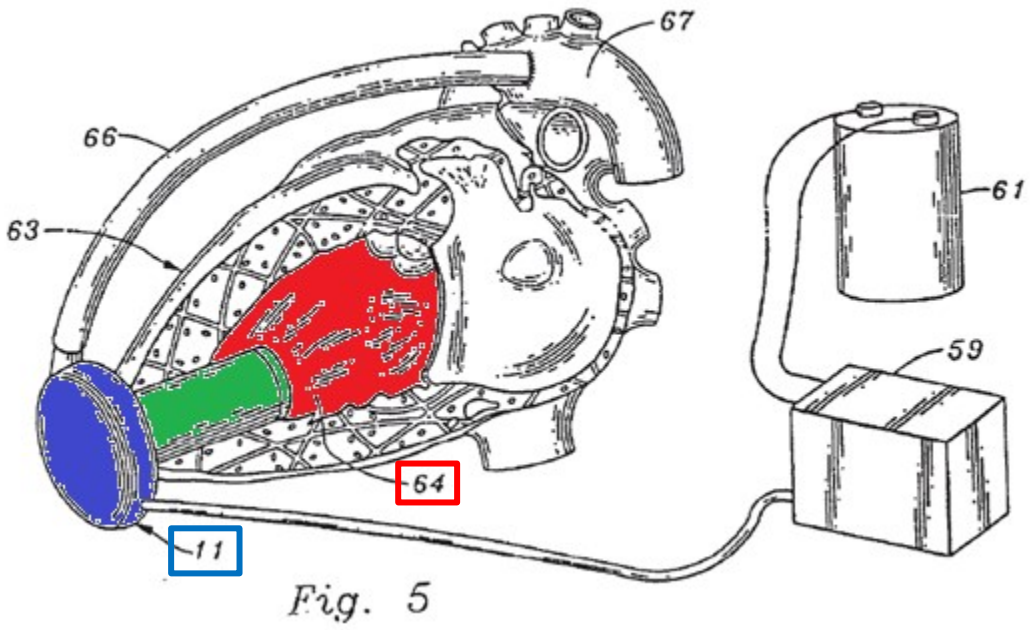
III along a central axis (**black**) and the flow path of blood from the left ventricle of the heart (**red** arrows):



Ex.1007 at Fig. 1B (annotated).

643. Wampler-169, however, recognized that the use of an elbow, such as in the Bourque 2001 device, was not necessary when using a centrifugal pump. Ex.1008, [0076]. Like the Bourque 2001 device, Wampler-169 also employs "a centrifugal design of the pump." Ex.1008, [0076]. Wampler-169 appreciated that "[t]he centrifugal design of the pump allows a considerable amount of flexibility during implantation." Ex.1008, [0076]. "Owing to the axial inflow and radial outflow of the pump," which is a characteristic feature of centrifugal pumps including the Bourque 2001 device, Wampler-169 explains that "a 90 degree

redirection of the blood is effected **without the necessity of a flow-restrictive elbow fitting**." Ex.1008, [0076]. With this design, "[g]ood anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076]. Consequently, "[t]he inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64," thereby eliminating the need for any elbow or additional inflow assembly, as shown below. Figure 5 (annotated) of Wampler-169 illustrates a representation of a human heart 63, showing the inlet tube 13 (**green**) of the pump 11 (**blue**) implanted within the left ventricle 64 (**red**) of the heart:



Ex.1008, Fig. 5.

644. In the combination of Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 (hereinafter Bourque/Wampler), the *axially aligned inflow tube* would have been implemented at the same location as the Bourque-2001 inflow tube so that "[t]he inlet tube…serves as the inflow cannula and is placed into the apex of the left ventricle" as taught by Wampler-169. Ex.1008, [0076].

645. Bourque-2001 and Wampler-169 are both analogous art to the 077 Patent for at least two reasons. *First*, Bourque-2001 and Wampler-169 are both directed toward **the same field of endeavor** of the 077 Patent—"to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via magneto coupling." Ex.1001, Abstract; 2:52-62 ("The embodiment to assist the performance of a heart according to the invention"). Bourque-2001 and Wampler-169 are within this same field of endeavor. Ex.1007 at 401 ("The HeartMate III…pump has no mechanical bearings [because] the rotor is magnetically suspended."); Ex.1008 at [0006], [0018] (An "implantable rotary sealless blood pump" that "advantageously" uses "magnets…in the pump drive system" such that "[t]orque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing.")

646. *Second*, Bourque-2001 and Wampler-169 are both reasonably **pertinent to a problem** described by the 077 Patent: reducing mechanical stress on the blood during pumping. *See, e.g.*, Ex.1001, 2:20-24 ("A fluid flow which is improved by the pump is to be developed in a way in which the mechanical stress of highly sensitive fluids, such as blood for example, can be kept as low as possible and nevertheless the corresponding improvement to circulation can be ensured at desired locations."). Both Bourque-2001 and Wampler-169 aim to address this problem. Ex.1007 at 401 ("The rotor is magnetically suspended, eliminating contact between moving parts" and resulting in "low hemolysis…and low thrombogenicity"); Ex.1008 at [0101] ("an improved sealless blood pump including magnetic bearings…to minimize thrombosis…[and] minimize hemolysis.").

647. It would have been obvious to combine Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 because to do so would have been the **arrangement of old elements** (substituting Bourque-2001's inflow assembly with Wampler-169's "inlet tube [which] serves as the inflow cannula and is placed into the apex of the left ventricle") with each performing the same function it has been known to perform (allowing blood to flow from the ventricle to the pump) and yielding no more than one would expect from such an arrangement (blood flowing

from the ventricle to the pump) as Wampler-169. Ex.1008 at [0075] ("The inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64.").

648. It would have also been obvious to combine Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 because a **POSITA would have been motivated** to do so based on the teachings of Wampler-169. For example, Wampler-169 teaches that a "centrifugal design…allows a considerable amount of flexibility during implantation" because "the axial inflow and radial outflow of the pump" means that "a 90-degree redirection of the blood is effected without the necessity of a flow-restrictive elbow fitting." Ex.1008 at [0076]. A POSITA would have recognized that, with the Wampler-169 configuration, "[g]ood anatomic compatibility is possible" so that the device "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex.1008, [0076].

649. Further, a **POSITA would have been motivated** to combine Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 based on the teachings of Bourque-2001. First, Bourque 2001 recognized that its elbow was a "flow-restrictive elbow" that cased flow "losses in transition"—the exact type of elbow that Wampler-169 taught to eliminate. Ex.1007 at 402 (the orientation of the pump "resulted in a sharp bend in the flow before it enters the impeller" which caused "[flow] losses in this transition…through this elbow"). Second, Bourque

2001 taught that the number of components of its inflow assembly caused "clinical troubles." Ex.1007 at 405 ("[I]tems such as cannula, grafts, articulating mechanical joints, [and] connectors…can account for most of the propensity for clinical troubles when implanted."). Ex.1007 at 405. But Bourque-2001 also taught that "[i]t was a fundamental goal of the HeartMate III mechanical design to achieve optimal pumping performance and…in the simplest possible way." Ex.1007 at 404. Ex.1006 at 3 ("The advantages of the rotary blood pump are its compactness, simplicity, and low cost."). Consequently, a POSITA would have been motivated to reduce the "clinical troubles" by designing the pump "in the simplest possible way" and by eliminating the flow-restrictive elbow and other components of the inflow assembly—i.e., the *axially aligned inflow tube* technique of Wampler-169.

650. It would have also been obvious to combine Bourque-2001 with the *axially aligned inflow tube* technique of Wampler-169 because a **POSITA would have been motivated** to do so based on the teachings that placement of LVADs in the preperitoneal pocket position were associated with increased infections rates and decreasing the size of LVADs was associated with reduced infection rates. For example, as discussed above, the larger early-generation LVADs required "surgical dissection" to place the device in a "pump pocket," which was associated with increased risk of infection. Ex.1014 at 842. The "increased rates" of infection

signaled a "need for further improvements in…the design of the device." Ex.1012 at 1442. Because the second-generation devices were smaller "and d[id] not require a great deal of surgical dissection," they had a "low[er] infection rate." Ex.1014 at 842. Although the smaller pump pocket dissection was smaller, it was still considered a disadvantage. For example, it was recognized that although "the pocket dissection is smaller with the HeartMate II [second-generation device],…potentially introducing less risk of infection," the "preperitoneal pocket position" was a "disadvantage[]" due to the "increased risk of infection" and "[p]otential for prolonged pocket drainage." Ex.1013 at 25-26. Further, A POSITA would have further been motivated to reduce rates of infection by adhering to Wampler-169's focus on "[g]ood anatomic compatibility" over Bourque-2001's focus on "borrowing" from "presently available Heart-Mate systems" like the "HeartMate II." Ex.1007, 403, 405. The HeartMate III's "elbow" "resulted" from a design "deci[sion]" "[t]o orient the pump" below the "diaphragm" in a preperitioneal pocket position, as shown:

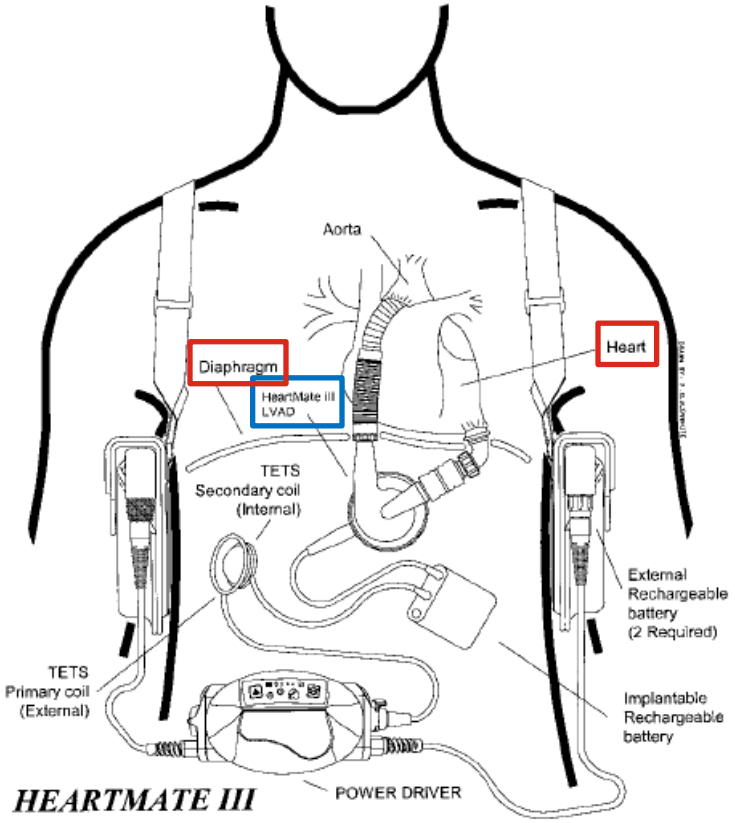


Figure 3. HeartMate III LVAD implanted configuration. TETS, transcutaneous energy transmission system.

Ex.1007, Fig. 3. This pocket position (below the diaphragm) resulted from Bourque-2001's aim to utilize the "peripheral hardware (i.e., inflow and outflow components)" of its predecessor "Heart-Mate systems." In addition to "borrowing" "inflow and outflow components" from the predecessor systems, Bourque-2001 also used similar "surgical techniques" for a "pump pocket dissection" as used to implant the "HeartMate II" below the diaphragm in a "preperitioneal pocket," as shown:

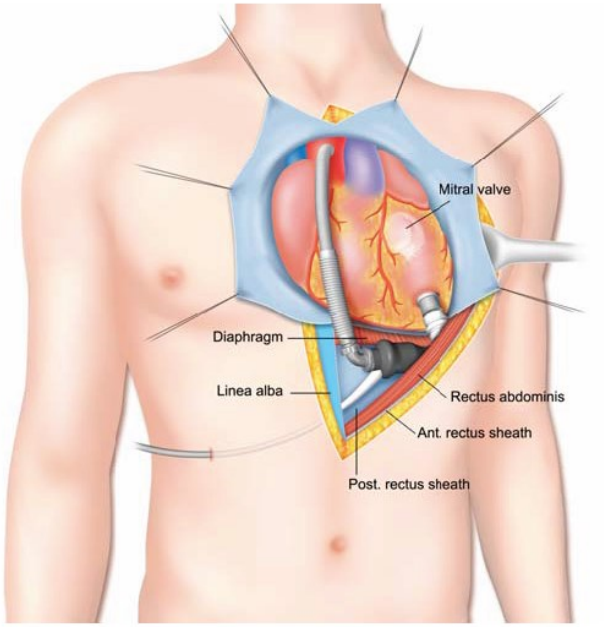


Figure 3: Preperitoneal placement of the HeartMate II pump (below the left rectus muscle and above the posterior rectus sheath).

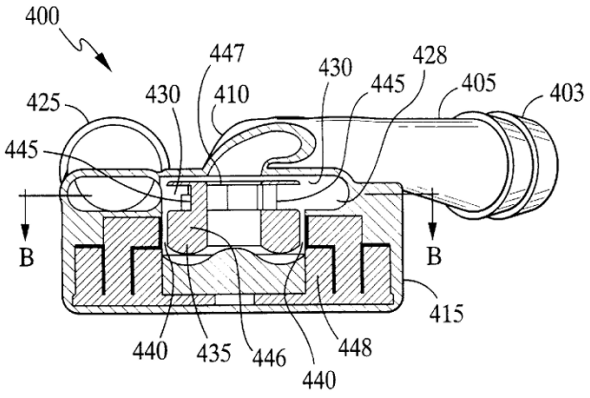
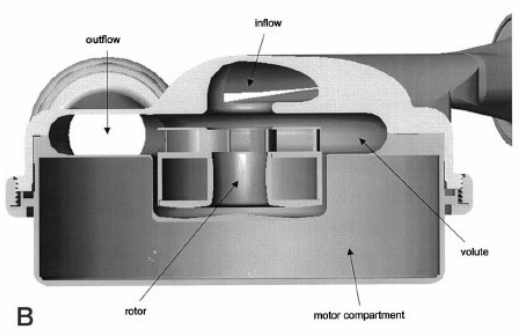
Ex.1013, 25. Indeed, both HeartMate II and III were "implanted…via left ventricular apical cannulation and anastomosis to the descending aorta." Ex.1007, 402, Ex.1013, 25, 57.

651. Bourque-2001 describes that its HeartMate III device would have been implanted in the same manner as "with presently available HeartMate systems," thus, a POSITA would have understood that it would have been placed at the preperitoneal pocket position. Ex.1007 at 405. A POSITA, however, would have recognized this to be a disadvantage with the Bourque-2001 device for the same reasons as recognized with the HeartMate I and HeartMate II systems described

above. Thus, a POSITA would have been motivated use the Bourque/Wampler combination, recognizing that such a configuration would enable the device to "fit[] well between the apex of the heart and the adjacent diaphragm" and eliminate the need for a dissection of and placement at the preperitoneal pocket position. Ex.1008, [0076]. Indeed, Wampler-169 is focused on "[a]natomical placement of the pump" and "[g]ood anatomic compatibility" so that the pump "fit[s] well between the apex of the heart and the adjacent diaphragm." Ex. 1008 at [0075]-[0076].

652. Further, a POSITA would have had a **reasonable expectation** that the Bourque/Wampler combination would be successful because the authors and engineers of Bourque-2001 taught that this specific modification was "not complex" and was "well-known in the art." Ex.1018 at 6:62-7:5. Victor L. Poirier is one of the engineers of Bourque-2001 HeartMate III device, co-author of Bourque-2001 reference, and also the inventor of U.S. Patent No. 6,050,975 (Ex.1018), assigned to Thoratec. The 975 patent issued on April 18, 2000, and is also prior art to the 077 Patent, and a POSITA exercising reasonable diligence could have located it. Further, Bourque-2001 and the 975 patent share common authors/inventors (and both worked for Thoratec), which is an additional reason that a POSITA would have looked to the teachings of the 975 patent.

653. The 975 Patent generally discloses two types of pumps, an axial flow blood pump (Fig. 1) and a centrifugal blood pump (Figs. 4-10). The HeartMate III design disclosed in Bourque-2001 is an embodiment of the 975 Patent's centrifugal blood pump (Figs. 4-10). For example, the following table illustrates a comparison between Figure 4B of the 975 Patent and the HeartMate III pump described in Bourque-2001:

975 Patent, Figure 4B	**Bourque 2001, Figure 1**
 FIG. 4B	

654. The 975 Patent's axial flow blood pump comprises an "inflow cannula apical tube 45, which is inserted into the apex of the left ventricle." 975 Patent at 4:43-46. The 975 Patent also describes that the centrifugal pump (e.g., Bourque-2001 HeartMate III) can be modified to use this inflow cannula from the axial flow blood pump:

> In the embodiment shown in FIGS. 4A-C, pump 400 can be attached to conventional tubing at adaptors 403 and 427

> to connect it between the left ventricle and aorta to provide ventricular assistance. In another embodiment, pump 400 may be implemented using various components of pump 10 modified to function with pump 400. For example, pump 400 may be modified to incorporate… **inflow cannula apical tube 45**…**The modifications required are not complex and are well-known in the art.**

Ex.1018 at 6:62-7:5. Thus, a POSITA would have had a reasonable expectation that the Bourque/Wampler combination would be successful, because the 975 patent teaches that modifying the Bourque-2001 with "an inflow cannula apical tube 45, which is inserted into the apex of the left ventricle," like the Wampler-169 technique is "not complex" and is "well-known in the art."

655. Further, a POSITA would have had a **reasonable expectation** of success that the Bourque/Wampler combination would "fit[] well between the apex of the heart and the adjacent diaphragm." Ex.1008 at [0075]. The Bourque-2001 HeartMate III was already planned for "enhancements [to] continue the progression of this LVAD's development as a compact" device (i.e., enhancements to make the device smaller), which would help its placement at the cardiac apex. Ex.1007 at 405. A POSITA also would have had a reasonable expectation of success because numerous other similar devices had already shown that an LVAD could fit well at that position. For example, in addition to Wampler-169, the Akamatsu-1999 device

described above similarly uses an inflow tube that is inserted into the left ventricle and fits at the cardiac apex so that the device sits within the pericardial space. Ex.1006 at Fig. 1. Further, the HVAD, another third-generation type device, reported that its "small size" allowed for an "optimized fit" because "[t]he pump ha[d] a short integrated inflow cannula and an axial height less than one inch, thus, [t]he size of the device coupled with the perpendicular relationship of outflow to the inflow allow[ed] for intrapericardial pump placement and fast implantation." Ex.1015. The fact that all these devices with similar designs fit well in the position at the apex of the heart would have given a POSITA a reasonable expectation of success that the Bourque/Wampler combination would also fit well.

656. Moreover, the Bourque/Wampler combination would have also been **obvious to try**. At the time of the claimed invention, it was within the general knowledge of a POSITA that the implantation of LVADs presented a finite number (i.e, two) options—the device could be implanted at a preperitoneal pocket or at the cardiac apex. To implant the device at the cardiac apex, a POSITA would have used the Bourque/Wampler combination, because that was the well-known technique for implanting at that position. *See* Ex.1006 at Fig. 1; Ex.1008 at [0075]-[0076]; Ex.1015. In doing so, a POSITA would have had a reasonable expectation of success

in view of the Wampler-169, Akamatsu-1999, and HVAD devices described above. Ex.1006 at Fig. 1; Ex.1008 at [0075]-[0076]; Ex.1015.

657. Accordingly, it would have been obvious to modify the Bourque-2001 device to include Wampler's techniques related to use of an *axially aligned inflow tube* to yield the Bourque/Wampler combination.

C. Ground 3: Akamatsu 1999 Renders Obvious Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent

1. Claim 1

i. [1PRE] A system for assisting the blood circulation of a heart, comprising:

658. To the extent that the preamble is a limitation, Akamatsu-1999 discloses "*a system for assisting the blood circulation of a* ***heart***."

659. For example, Akamatsu-1999 describes that at the time "[r]otary blood pumps, such as the axial flow pump and the centrifugal pump, [were] being developed worldwide as implantable ventricular assist systems (VAS)." Ex.1006 at 3. However, "the conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and the seal." Ex.1006 at 6. The study described in Akamatsu-1999 discusses the development of an improved blood pump, a "totally implantable left ventricular assist system (T-ILVAS)," which uses "a centrifugal pump with a magnetically suspended impeller

(MSCP)," which "operates completely contact-free without any material wear." Ex.1006 at 3, 7. The T-ILVAS, including the centrifugal pump (**blue**), in its implanted configuration with the inlet port placed in the left ventricle of the heart (**red**) of a body is illustrated in Figure 1, annotated:

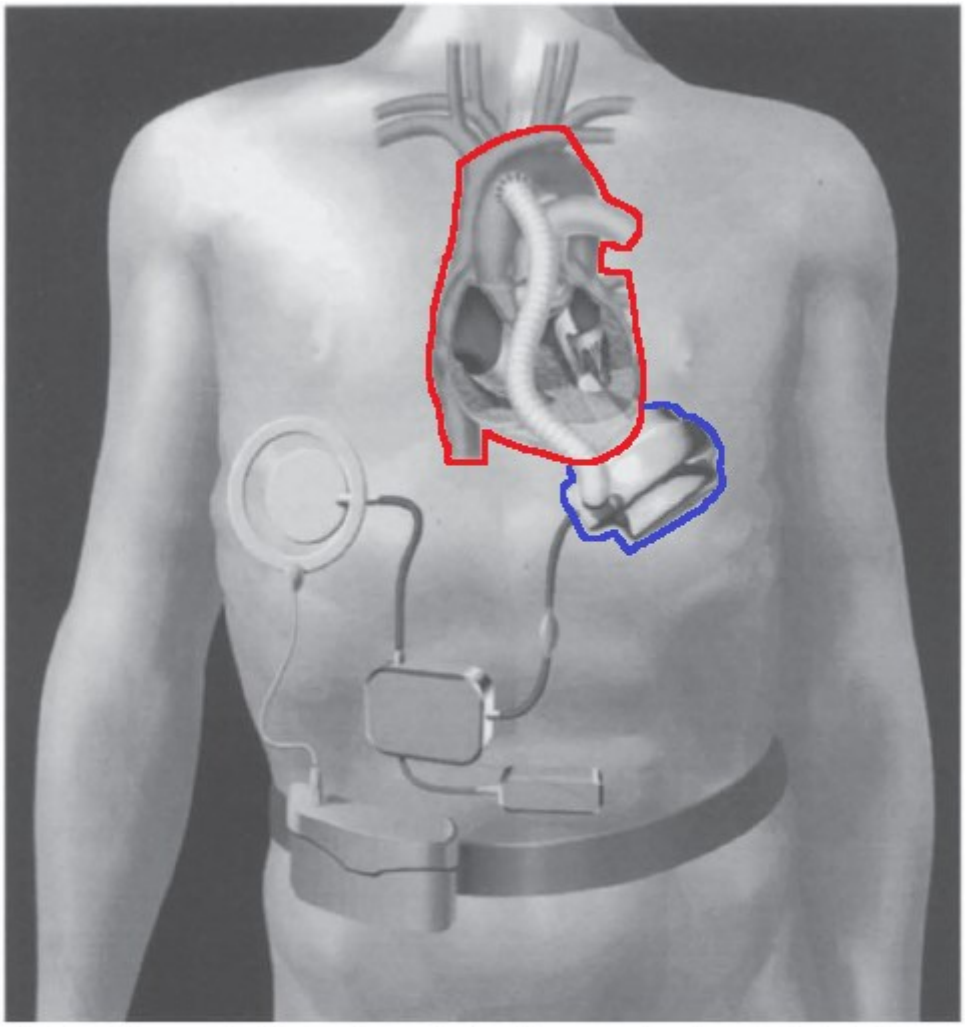


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

660. Accordingly, Akamatsu-1999 discloses "*a system for assisting the blood circulation of a* ***heart***."

ii. [1A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart

661. Akamatsu-1999 discloses "***a heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** *and having a suction end insertable into* ***a ventricle of the heart***."

662. The 077 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device deliverable to the heart" includes "an inflow cannula…inserted into a left ventricle of a patient's heart." *See* Ex.1019, (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "a heart assist pump device deliverable to the heart."

663. Accordingly, Akamatsu-1999 discloses that the described "totally implantable left ventricular assist system (T-ILVAS)" includes a "sealless centrifugal pump." Ex.1006 at 3, 5. The T-ILVAS also includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured

to the left ventricular apex" during the *ex vivo* study performed on sheep. Ex.1006 at 4. During testing, "[t]he pump operated at a fixed rotational speed" and "aortic pressure and pump flow rate were continuously measured." Ex.1006 at 4. The pumps were "intrathoracically implanted" (i.e., implanted in the thorax) of the sheep. Ex.1006 at 5.

664. Figure 2 (annotated) illustrates a cross section of the centrifugal pump of the T-ILVAS, which includes an "inlet port" (**green**) having a suction end, as indicated by the arrows illustrating blood being directed through the inlet port:

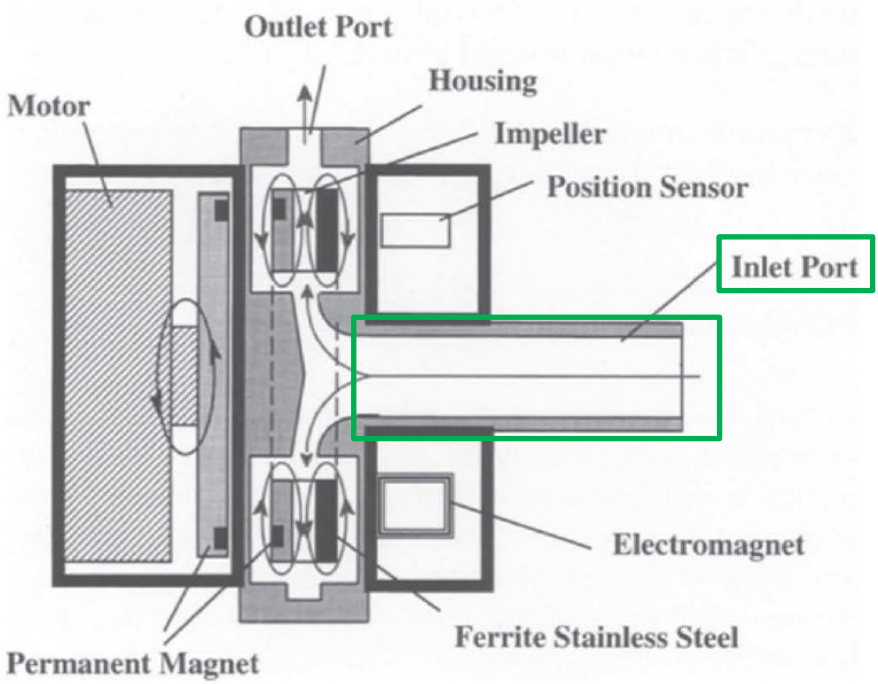


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2. Note that Figure 2 is a cross-sectional view of the centrifugal pump and the inlet port is understood to be in the shape of a tube that surrounds the central axis. Thus Figure 2 shows the inlet port as a rectangular cross sections.

665. In addition, Figure 1 (annotated) illustrates the T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inlet port [‘*suction end of an inflow tube*’] (**green**) of the T-ILVAS is inserted into the left ventricle of the heart:

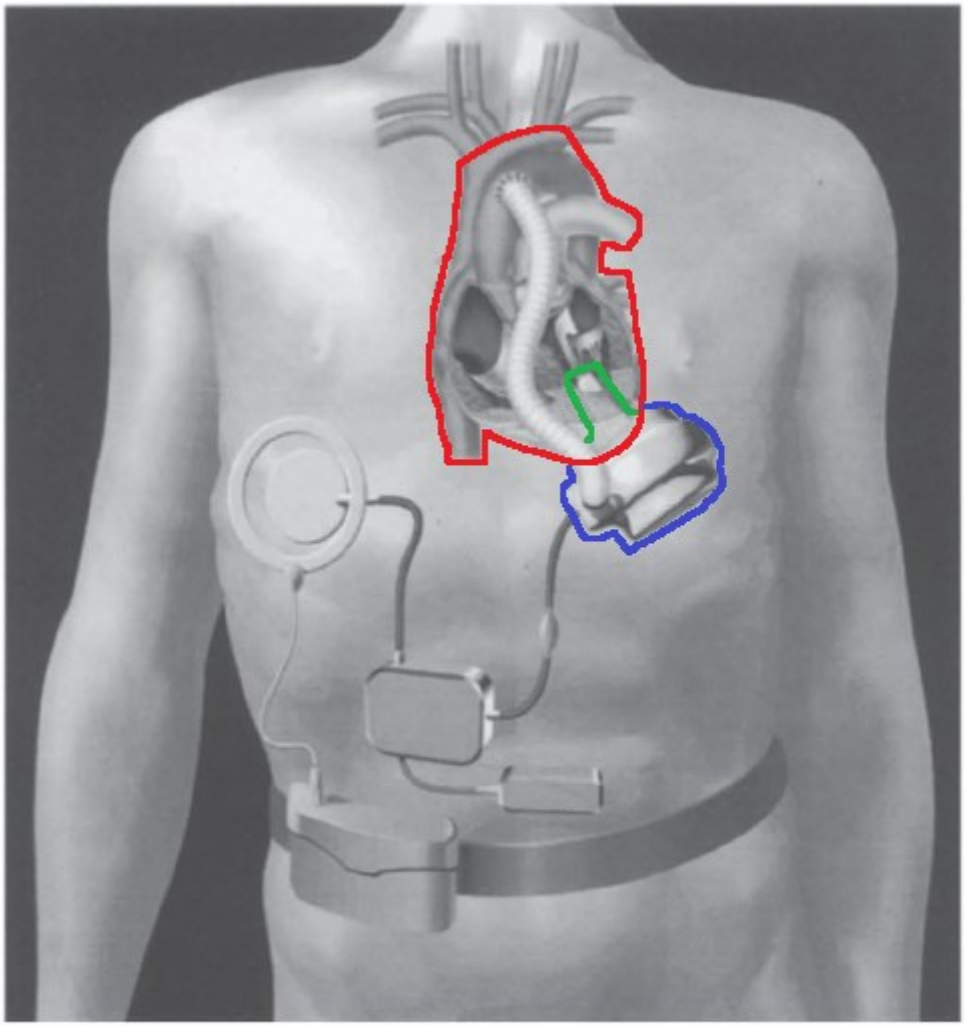


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

666. Accordingly, Akamatsu-1999 discloses "***a heart assist pump device*** ("centrifugal pump") *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** ("inlet port") *and having a suction end insertable into* ***a ventricle of the heart*** ("inserted into the left ventricle")."

iii. [1B] a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle

667. Akamatsu-1999 discloses that "*a **magnetically driven rotor assembly** configured to be axially aligned with the **inflow tube** and to be spaced apart from the suction end when the **suction end of the inflow tube** is inserted into the **ventricle**.*"

668. For example, Akamatsu-1999 discloses that the T-ILVAS includes "a centrifugal blood pump with a magnetically suspended impeller (MSCP)." Ex.1006 at 3; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material, it is expected to be one of the most durable blood pumps."). "The impeller is suspended by a magnetic bearing, thus providing contact-free rotation of the impeller inside the pump." Ex.1006 at 3.

669. An "impeller" is a commonly used type of rotor that provides the pumping action when used in reference to a centrifugal pump, such as the "centrifugal pump" described in Akamatsu-1999. I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that maps the impeller portion of the "rotor" of the "HeartMate 3" to the "magnetically driven rotor" element recited in Claim 1. *See* Ex.1019, at pp. 5 (Complaint, Ex. 12). For

the purposes of my analysis, I map the limitation of a "magnetically driven rotor" to the "impeller" described in Akamatsu-1999 in the same way.

670. Thus, based on the disclosures above, the "impeller" of the centrifugal pump described in Akamatsu-1999 is a "**rotor**."

671. Akamatsu-1999 further discloses that the "impeller" of the centrifugal pump is "**magnetically driven**" as recited in claim 1. For example, Akamatsu-1999 discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear."). As illustrated in Figure 2 of Akamatsu-1999, the "DC brushless motor"[19] rotates a plate having embedded a "permanent magnet." Ex.1006,

[19] The first "Brushless DC Motor" was invented in 1962 (Wilson, T. G., and P. H. Trickey. "DC machine with solid-state commutation." *Electrical Engineering* 81.11 (1962): 879-884) and has been commonly used for decades, for example, in household appliances like washing machines, computer equipment and many cordless tools. Brushless DC motor theory and practice would have been part of an undergraduate engineering course from about the 1980s, and therefore would have been well known to a POSITA at the time of the alleged invention on February 27, 2007. *See also* "Brushless DC Motors," National Aeronautics and Space Administration (NASA), NASA CR-2506, (January 1975) (accessed at https://ntrs.nasa.gov/api/citations/19750007247/downloads/19750007247.pdf).

Fig. 2. The rotation of the motor's "permanent magnet" creates a torque on the impeller because of the attractive magnetic force between the permanent magnet embedded in the motor plate and the permanent magnet embedded in the impeller. Ex.1006 at 4, Fig. 2. As detailed below with respect to element [1C], these permanent magnetic segments are **permanent magnet**, which are rigidly coupled and axially adjacent the **impeller**.

672. Thus, the **impeller** together with the **permanent magnet** described in Akamatsu-1999 are a **magnetically driven rotor assembly** because together they form a rotor driven by the force generated by the electromagnetic field created between the "permanent magnet" within the impeller and the "permanent magnet" of the DC brushless motor. *See infra* Sections X.C.1.iv and X.C.1.viii; Ex.1006 at 4, Fig. 2, 5.

673. For components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis") in space. The centrifugal pump described in Akamatsu-1999 has a central axis that is configured in axial alignment with the **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4) so as to provide the flow of blood to the **magnetically driven rotor** (e.g., "impeller," and "permanent magnet" Ex.1006 at 4). For example, Figure 2 (annotated) of Akamatsu-1999 illustrates the alignment of the impeller (**pink**) and

the inlet port (**green**) of the centrifugal pump along a central axis and the flow path of blood from the left ventricle the heart (**red** arrows):

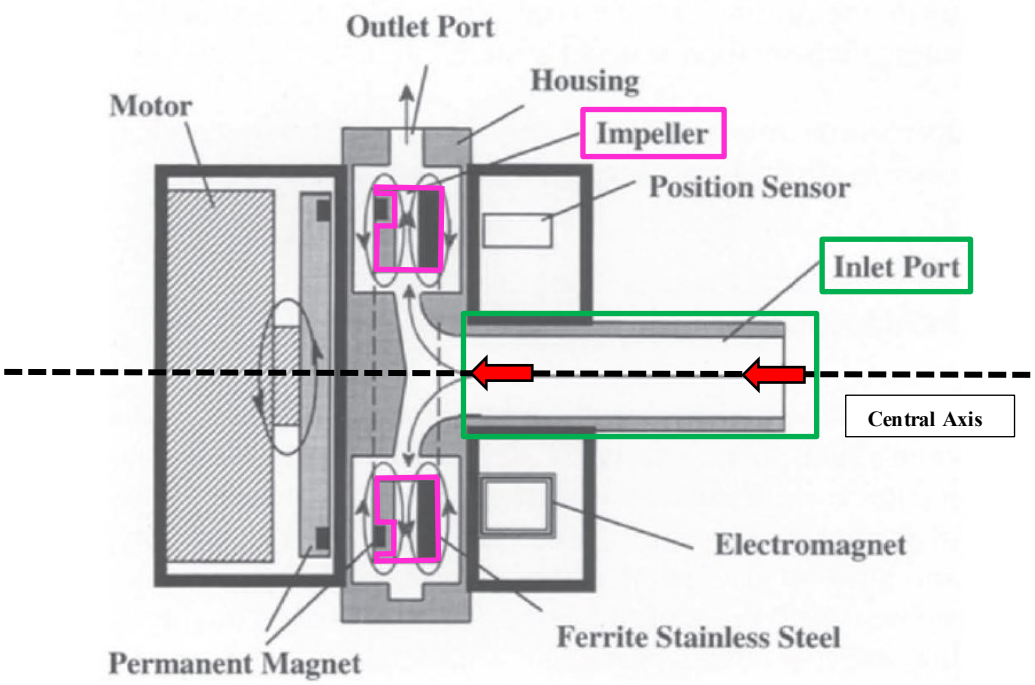
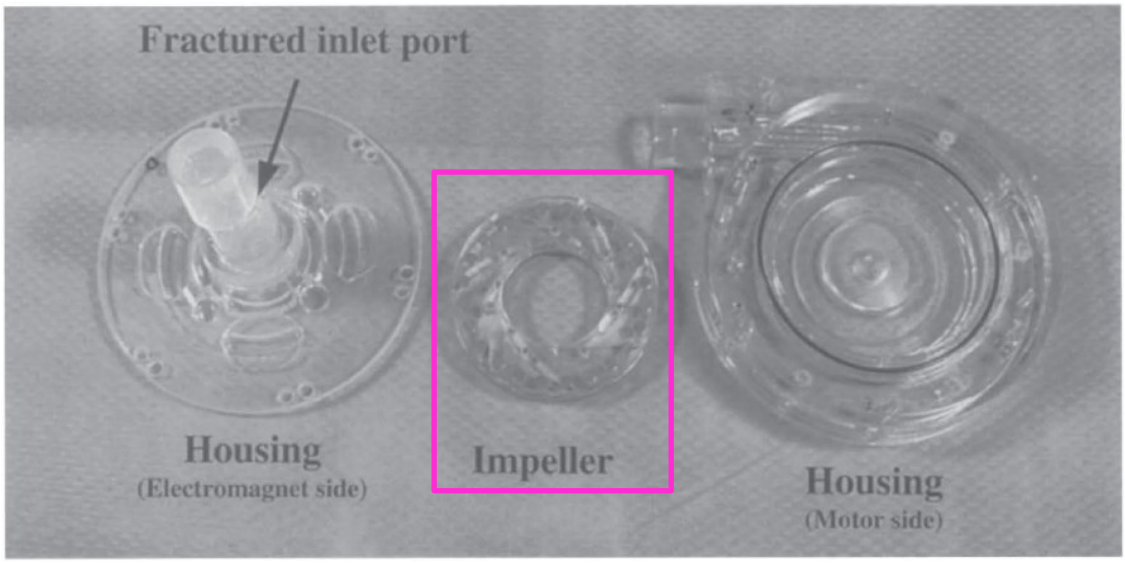


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

674. Indeed, the pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the rotating impeller and is accelerated by centrifugal force toward the circumference of the impeller, collected by a volute and then discharged through an outlet port. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

675. Figure 5 (annotated) illustrates a top view of the impeller (**pink**) separated from the housing of the pump after testing:



Ex.1006, Fig. 5 (annotated).

676. Finally, Figure 1 (annotated) illustrates that the centrifugal pump (**blue**), which includes the impeller in its housing, is positioned outside the heart (**red**) and spaced apart from the suction end of the inlet port [‘*suction end of an inflow tube*’] (**green**) inserted into the left ventricle of the heart:

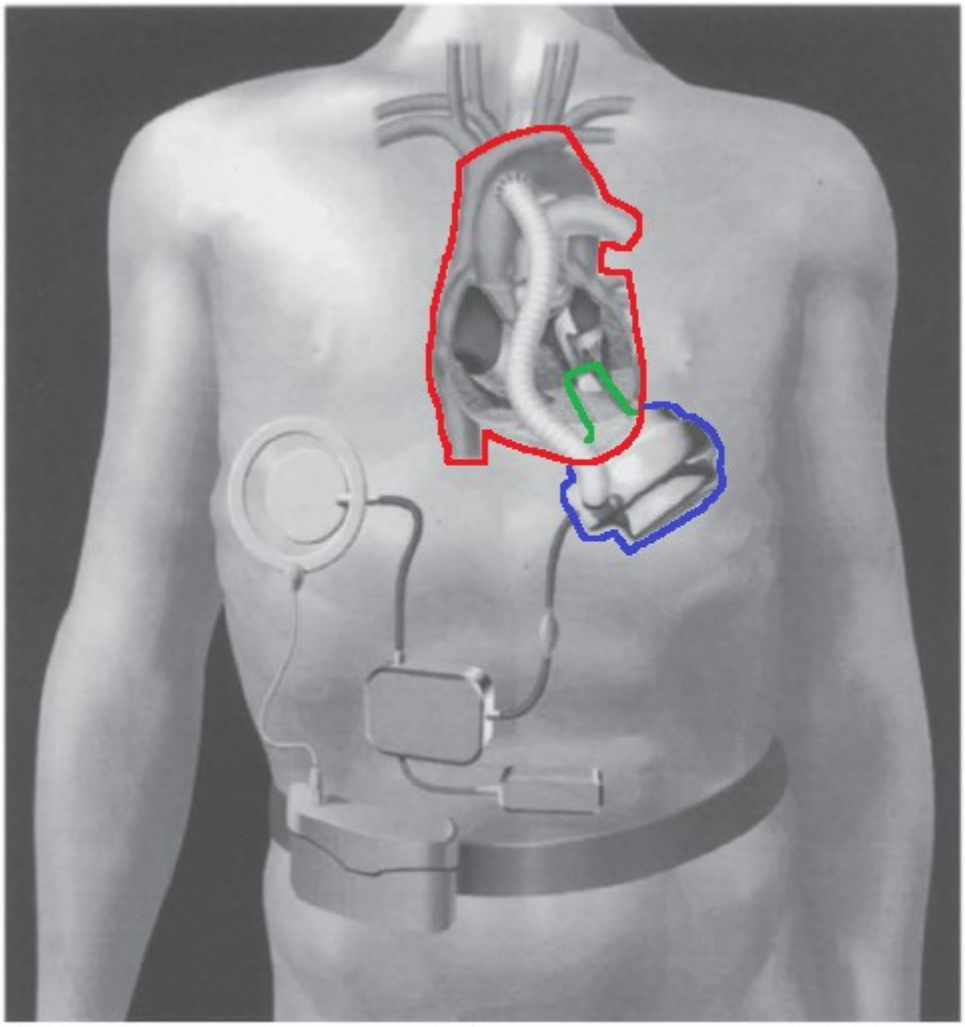


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

677. Accordingly, Akamatsu-1999 discloses "*a* ***magnetically driven rotor assembly*** ("impeller" and "permanent magnet") *configured to be axially aligned with the* ***inflow tube*** ("inlet port") *and to be spaced apart from the suction end when the* ***suction end of the inflow tube*** *is inserted into the* ***ventricle***."

iv. [1C] the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor

678. Akamatsu-1999 discloses "*the **magnetically driven rotor assembly** comprising a **first magnetic device** that is rigidly coupled to and axially adjacent to a **rotor**.*"

679. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **permanent magnets** which are rigidly coupled and axially adjacent the **impeller**.

680. Akamatsu-1999 discloses that the centrifugal pump "is composed of four parts: a magnetic bearing, an impeller, a housing, and a DC brushless motor." Ex.1006 at 4. "The impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4. As illustrated in Figure 2 of Akamatsu-1999, the impeller has a "permanent magnet" located within it. Ex.1006, Fig. 2. As discussed with respect to element [1B], the "impeller" is a **magnetically driven rotor**. *See* Section X.C.1.iii. The "permanent magnet" located within the impeller is a **first magnetic device** which is rigidly coupled to the **magnetically driven rotor** because it is located within the impeller.

681. As will be discussed with respect to elements [1G] and [1J], the "DC brushless motor" rotates a plate having a "permanent magnet." Ex.1006, Fig. 2. The rotation of the motor's "permanent magnet" creates a torque on the impeller because of the attractive magnetic force between the permanent magnet sealed in the motor plate and the permanent magnet sealed in the impeller. Ex.1006 at 4, Fig. 2; *see infra* Sections X.C.1.viii, X.C.1.xi, and X.C.1.xii. In order to generate the torque to rotate the impeller, the "permanent magnet" is axially adjacent to the impeller such that, when the magnetic force is applied, the impeller may rotate about its axis. Ex.1006 at 4.

682. Figure 2 (annotated) illustrates a cross-sectional view of the pump where the "permanent magnet" (**purple**) is axially adjacent the impeller (**pink**) along the central axis (**black**) in order to drive rotation, as indicated by the arrows surrounding the shaft from the motor driving the plate holding the permanent magnets:

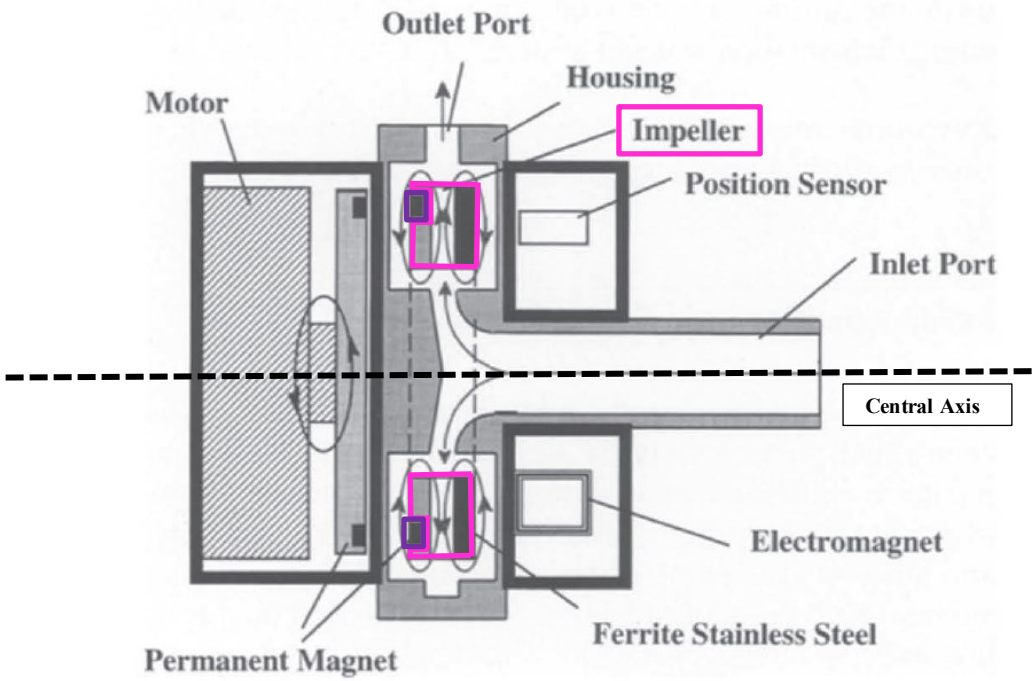


Fig. 2. Schematic cross section of the MSCP

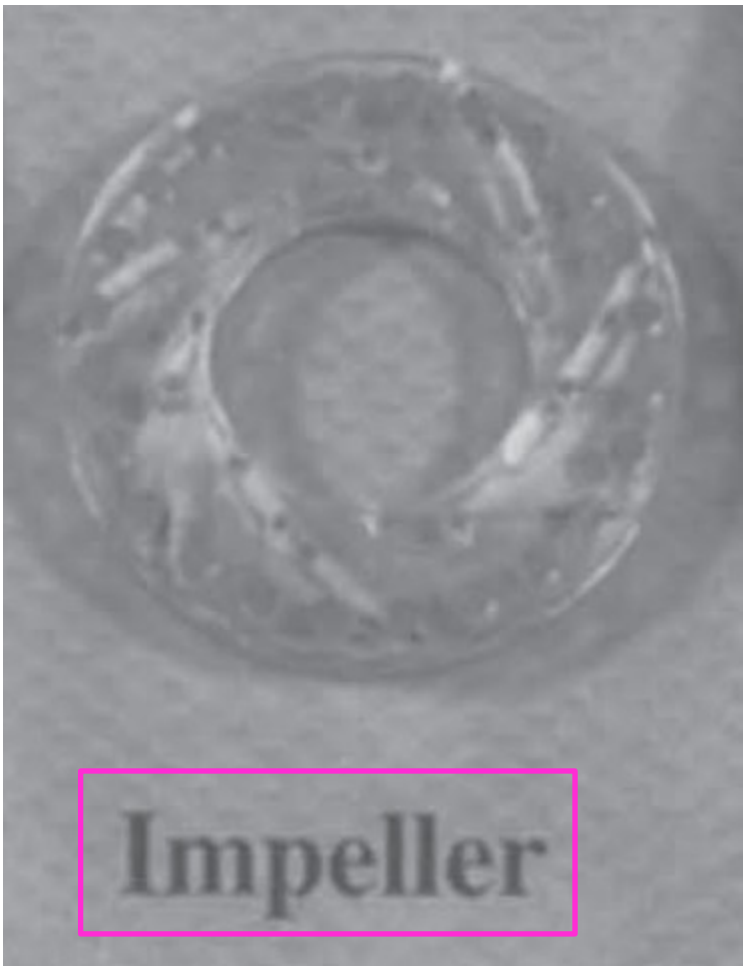
Note that Figure 2 is a cross-sectional view of the centrifugal pump and the impeller, including its permanent magnet, is understood to radially surround the central axis.

683. Accordingly, Akamatsu-1999 discloses "*the **magnetically driven rotor assembly*** ("impeller" and embedded "permanent magnets") *comprising a **first magnetic device*** (impeller's "permanent magnet") *that is rigidly coupled to and axially adjacent to a **rotor***."

v. [1D] [the rotor] having guide surfaces to produce centrifugal flow components

684. Akamatsu-1999 discloses that the **rotor** *"having guide surfaces to produce centrifugal flow components*." As will be discussed with respect to element [1G], Akamatsu-1999 discloses a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). *See supra* Section X.C.1.viii.

685. An isolated portion of Figure 5 (annotated) of Akamatsu-1999 shows a top view of the impeller (**pink**) removed from the housing and having guide surfaces that produce "centrifugal flow components":



Ex.1006, Fig. 5 (annotated).

686. Indeed, the pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. *See, e.g.*, Ex.1006 at 3

("***Rotary blood pumps***, such as the axial flow pump and the ***centrifugal pump***, are being developed worldwide ventricular assist systems (VAS)."). An impeller has blades or edges (i.e., "guide surfaces") which push fluid radially, imparting kinetic energy to the fluid resulting in increased pressure. Said another way, the production of centrifugal flow components by the guide surfaces of the impeller are a characteristic feature of a centrifugal pump.

687. Accordingly, Akamatsu-1999 discloses the **rotor** ("impeller") "*having guide surfaces to produce centrifugal flow components*."

vi. [1E] the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor

688. Akamatsu-1999 discloses "*the **magnetically driven rotor assembly** being rotatable about a **central axis** within **a surrounding stationary housing** to act upon blood flowing from the **inflow tube** to the **rotor**.*"

689. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **permanent magnets** which are rigidly coupled and axially adjacent the **impeller**.

690. Further, Akamatsu-1999 discloses that the centrifugal pump includes a "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the

electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."). The "impeller" is a **magnetically driven rotor**. *See* Section X.C.1.iii.

691. Thus, the "housing" of the centrifugal pump is a **surrounding stationary housing** which houses a **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 5).

692. Akamatsu-1999 further discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets." Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear."), 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is expected to be one of the most durable blood pumps."). Thus, the **magnetically driven rotor assembly** (e.g., "impeller" and "permanent magnets") rotatable within a **surrounding stationary housing** (e.g., "a housing") of the centrifugal pump to act upon blood flowing from the "inlet port" or "inflow conduit" toward the impeller.

693. Figure 2 (annotated) illustrates the impeller (**pink**) and permanent magnets (**purple**) rotatable about the central axis within the housing (**orange**) of the

centrifugal pump to generate a "pump flow rate" from the inlet port (**green**) toward the impeller (**black** arrows):

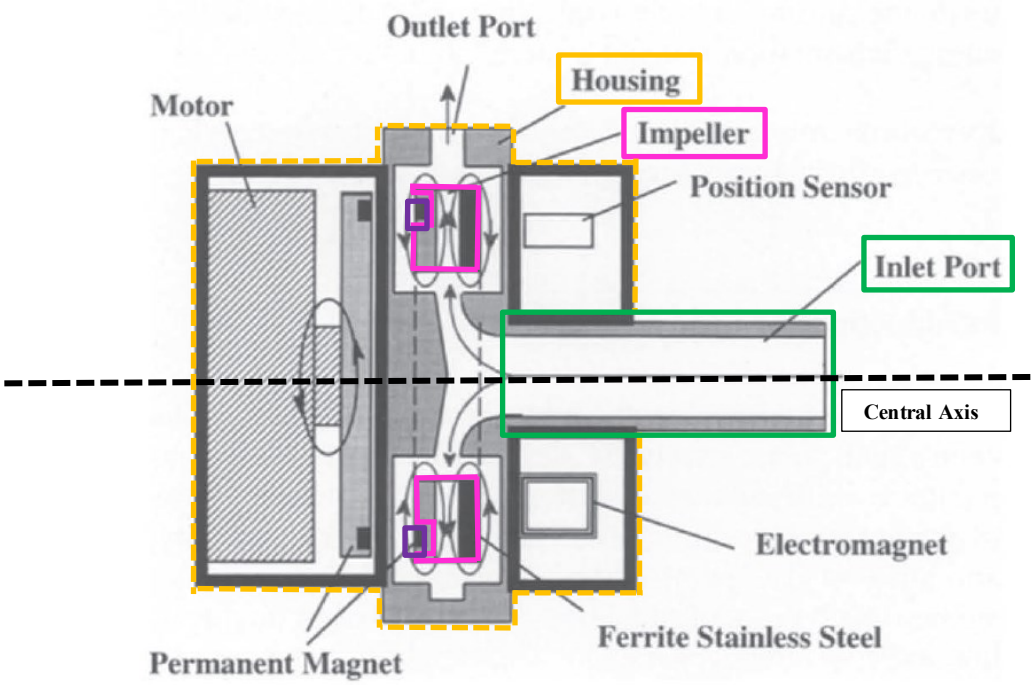
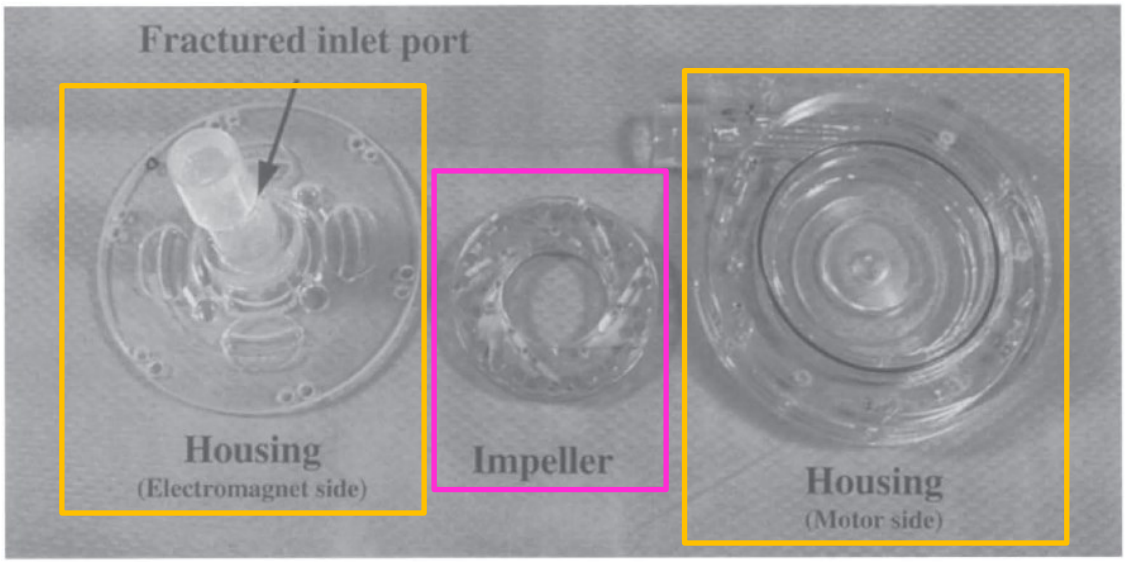


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

694. Figure 5 (annotated) illustrates a top view of the impeller (**pink**) and the "motor side" and "electromagnet side" which form the housing (**orange**) enclosing the impeller, in which each component was separated out after testing:



Ex.1006, Fig. 5 (annotated).

695. Accordingly, Akamatsu-1999 discloses "*the **magnetically driven rotor assembly*** ("impeller" and embedded "permanent magnets") *being rotatable about a **central axis** within **a surrounding stationary housing*** ("housing") *to act upon blood flowing from the **inflow tube*** ("inlet port") *to the **rotor*** ("impeller")."

vii. [1F] while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for the passage of the blood;

696. Akamatsu-1999 discloses that "*the **magnetically driven rotor assembly** is entirely spaced apart from the **stationary housing** by a gap sized for the passage of the blood*." *See supra* Section X.C.1.iii.

697. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **permanent magnets** which are rigidly coupled and axially adjacent the **impeller**.

698. As discussed below with respect to element [1G], Akamatsu-1999 discloses a "magneto coupling" such that the impeller "is suspended magnetically by the three electromagnets" which comprise the "magnetic bearing." Ex.1006 at 4. "The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing ***contact-free rotation*** of the impeller without any material wear it is expected to be one of the most durable blood pumps."). The V-ILVAS Model II used during testing "had a single electric wire, with the intrahousing connectors between the motor and the electromagnets." Thus, in response to the rotation of the impeller by motor via the magneto coupling, the impeller remains spaced apart from the housing using the electromagnets, which interact with the "ferrite stainless steel" portion of the impeller, as shown in Figure 2.

699. For example, Figure 2 (annotated) illustrates that the magneto coupling orients the impeller (**pink**) such that in response to the rotation of the impeller (shown by the circular arrows surrounding the shaft of the motor driving the plate

holding the permanent magnets), the impeller is spaced apart from the housing (**orange**) by the gap between the impeller and housing for blood passage:

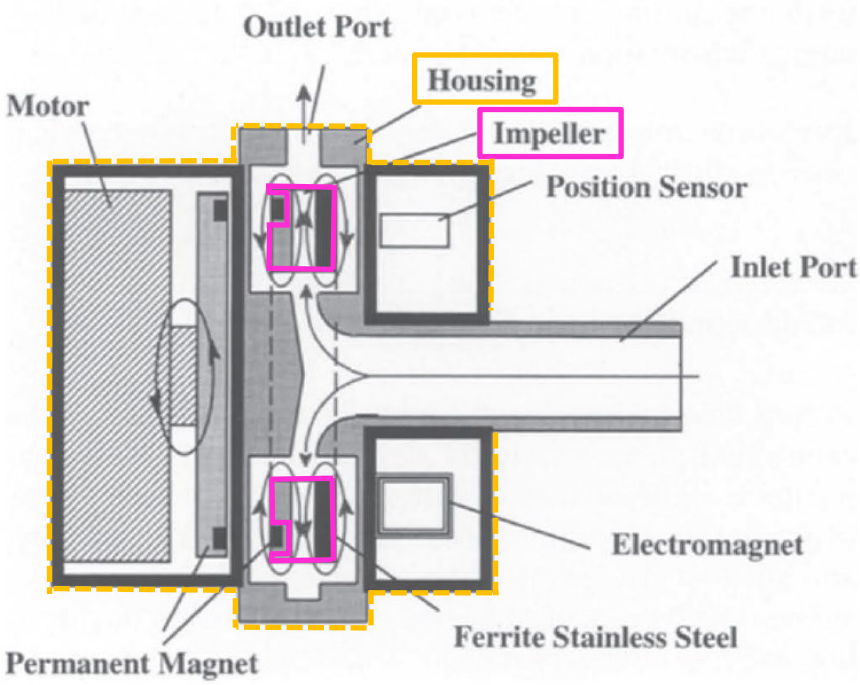


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

700. Thus, for the same reasons as discussed with respect to element [1G] below, Akamatsu-1999 discloses that the **magnetically driven rotor assembly** ("impeller"), is entirely spaced apart from the **stationary housing** ("housing") by a gap (e.g., "contact-free rotation of the impeller inside the pump," Ex.1006, at 4").

701. Accordingly, Akamatsu-1999 discloses that "*the **magnetically driven rotor assembly** is entirely spaced apart from the **stationary housing*** ("housing") *by a gap sized for passage of the blood.*"

viii. [1G] a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device

702. Akamatsu-1999 discloses that "*a **second magnetic device** axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** via a magneto coupling with the **first magnetic device**.*"

703. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **permanent magnets** which are rigidly coupled and axially adjacent the **impeller**.

704. Further, as discussed above with respect to element [1B], for components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *See supra* Section X.C.1.iii. The **heart assist pump device** (e.g., "centrifugal pump," Ex.1006 at 3-4) described in Akamatsu-1999 has an **inflow tube** (e.g., "inlet port" or "inflow conduit," Ex.1006 at 4) through which blood flows to the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4), which is driven by the magnetic coupling between the **first magnetic device** (e.g., the "permanent magnet"

within the impeller, Ex.1006, Fig. 2) and the **second magnetic device** (e.g., the "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 8).

705. Each of the impeller and its permanent magnet, and the DC brushless motor and its permanent magnet described in Akamatsu-1999 are axially aligned with the inlet port or inflow conduit. Ex.1006, Fig. 2. Indeed, the centrifugal pump described in Akamatsu-1999 is a *centrifugal* pump, and by design, fluid enters a centrifugal pump along its axis towards the impeller and is cast out by centrifugal force along its circumference. Said another way, an axially aligned inflow tube is a characteristic feature of a centrifugal pump.

706. Figure 2 (annotated) illustrates a cross-sectional view of the pump where the "DC brushless motor" (**light blue**), including its "permanent magnet," is axially aligned with the inlet port (**green**) along the central axis (**black**):

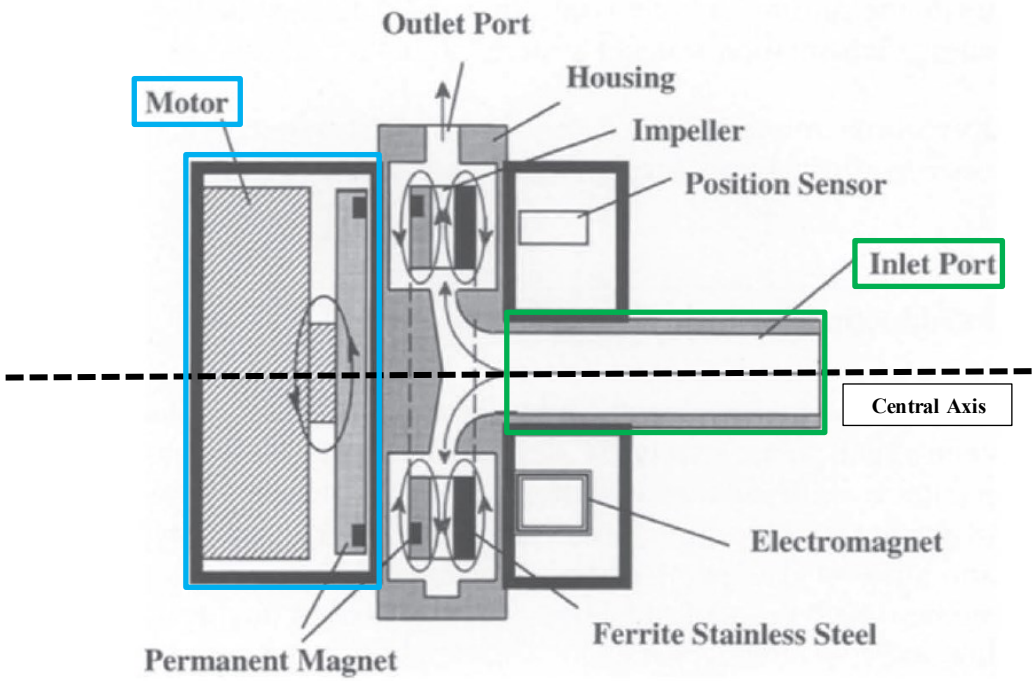


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

707. As discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. For the purposes of my analysis in this Ground, I assume that my narrower interpretation of the plain and ordinary meaning is correct, and Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also to include "a transfer of torque from one *stationary*

magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is incorrect. *See* Ex.1019.

708. Accordingly, based on my understanding of the term "magneto coupling," Akamatsu-1999 describes a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). For example, Akamatsu-1999 discloses that the "impeller rotates by a ***magnetic coupling*** between the impeller and the motor." Ex.1006, [0072]; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing contact-free rotation of the impeller without any material wear it is expected to be one of the most durable blood pumps."). Akamatsu-1999 discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear." Ex.1006 at 6.

709. As shown in Figure 2, the T-ILVAS achieves this "contact-free" rotation of the impeller because the "DC brushless motor" rotates a plate having a "permanent magnet," which creates a torque on the impeller because of the attractive magnetic force (or "magnetic coupling") between the permanent magnet rotated by the motor and the permanent magnet within the impeller. Ex.1006 at 4, Fig. 2. That is, the rotation of the impeller is locked against relative rotation of the motor plate.

710. This "magnetic coupling" described in Akamatsu-1999 is the same type of transfer of torque using "magneto coupling" described in the 077 Patent. *See, e.g.*, Ex.1001, 3:59-64 ("The rotation of the paddle wheel 21 is regulated here accordingly by corresponding control of the fluid pressure in the lumen 22 serving for the supply of fluid, in which ***the [rotor] magnet 19, which is connected so as to be locked against relative rotation with the paddle wheel 21, is set into corresponding rotation***.").

711. Figure 2 (annotated) of Akamatsu-1999 illustrates that the "DC brushless motor" (**light blue**), including its "permanent magnet," is positioned to magnetically drive rotation of the impeller (**pink**) via a magneto coupling with the permanent magnet (**purple**) within the impeller:

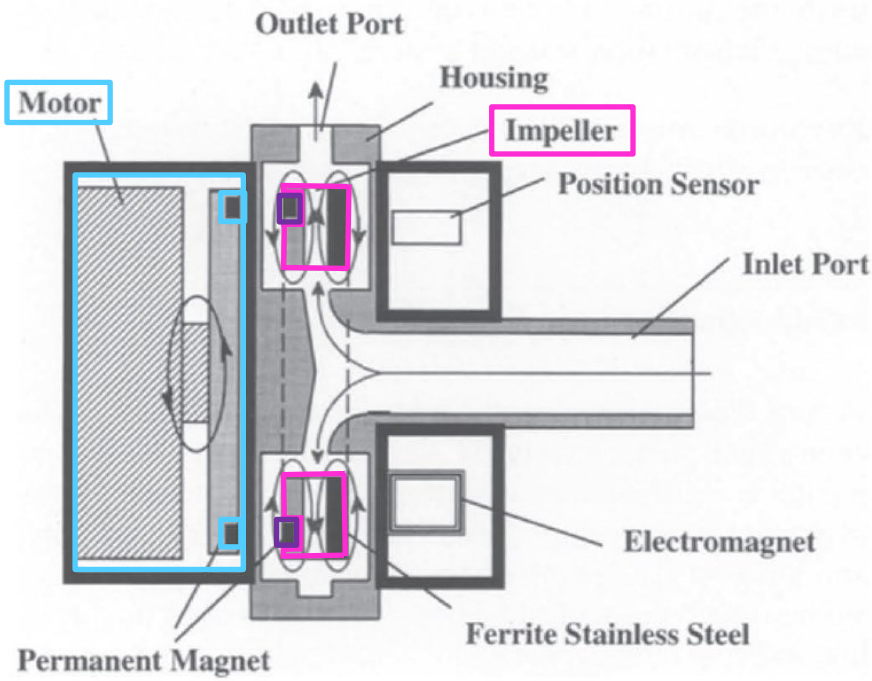


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

712. Note that Figure 2 is a cross-sectional view of the centrifugal pump and the impeller, including its permanent magnet, is understood to surround the central axis, essentially mirroring the rotation of the permanent magnet within the motor.

713. Accordingly, Akamatsu-1999 discloses that "*a **second magnetic device*** ("DC brushless motor") *axially aligned with the **inflow tube*** ("inlet port") *and positioned to magnetically drive rotation of the **magnetically driven rotor assembly*** ("impeller" and "permanent magnet") *via a magneto coupling with the **first magnetic device*** (impeller's "permanent magnet")."

ix. [1H] while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly

714. Akamatsu-1999 discloses that the **second magnetic device** is positioned according to element [1K] "*while being spaced apart and sealed from both the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly.***"

715. As discussed with respect to element [1E], Akamatsu-1999 discloses that the centrifugal pump includes an "impeller" and "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."); *supra* Section X.C.1.vi. The "impeller" is a **magnetically driven rotor**. *See supra* Section X.C.1.iii. And as discussed with respect to element [1C], the "permanent magnet" within the impeller is a **first magnetic device**. Ex.1006, [0070], [0064]; *supra* Section X.C.1.iv.

716. Akamatsu-1999 further discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to

obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a ***sealless centrifugal pump*** with a magnetically suspended impeller (MSCP), which operates completely ***contact-free*** without any material wear." Ex.1006 at 6. While Akamatsu-1999 reported a "leakage of blood into the electromagnets" during one study, that issue was resolved—"[t]he connector system of the Model II pump was changed to a dual-wired system"—to seal the electromagnets and from the pump housing.

717. Thus, the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) is spaced apart and sealed from the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2).

718. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross-sectional view of the centrifugal pump having a DC brushless motor (**light blue**) that is spaced apart and sealed from the impeller (**pink**), including a permanent magnet (**purple**), as indicated by the solid black line surrounding the motor:

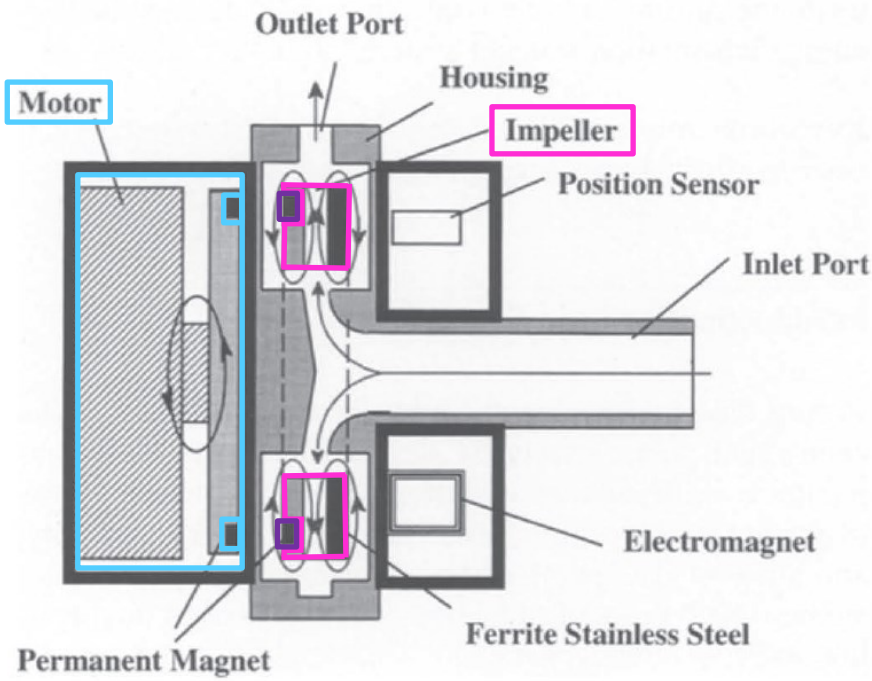


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

719. Accordingly, Akamatsu-1999 discloses that the **second magnetic device** ("DC brushless motor") is positioned according to element [1H] "*while being spaced apart and sealed from both the* ***rotor*** ("impeller") *and the* ***first magnetic device*** (impeller's "permanent magnet") *of the* ***magnetically driven rotor assembly***."

x. [1I] the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor

720. Akamatsu-1999 discloses that "*the* ***second magnetic device*** *being positioned axially spaced apart from the guide surfaces of the* ***rotor***."

721. As discussed with respect to element [1D], the **rotor** comprises guide surfaces to produce centrifugal flow components.

722. As discussed with respect to element [1H], Akamatsu-1999 discloses that the centrifugal pump includes an "impeller" and "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."); *supra* Section X.C.1.ix. The "impeller" is a **magnetically driven rotor**. *See supra* Section X.C.1.iii.

723. Akamatsu-1999 further discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a ***sealless centrifugal pump*** with a magnetically suspended impeller (MSCP), which operates completely ***contact-free*** without any material wear." Ex.1006 at 6. While Akamatsu-1999 reported a "leakage of blood into the electromagnets" during one study, that issue was resolved—"[t]he connector system of the Model II pump was

changed to a dual-wired system"—to seal the electromagnets and from the pump housing.

724. Thus, the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) is spaced apart and sealed from the **magnetically driven rotor** (e.g., "impeller," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2).

725. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross-sectional view of the centrifugal pump having a DC brushless motor (**light blue**) that is spaced apart and sealed from the impeller (**pink**), including a permanent magnet (**purple**), as indicated by the solid black line surrounding the motor:

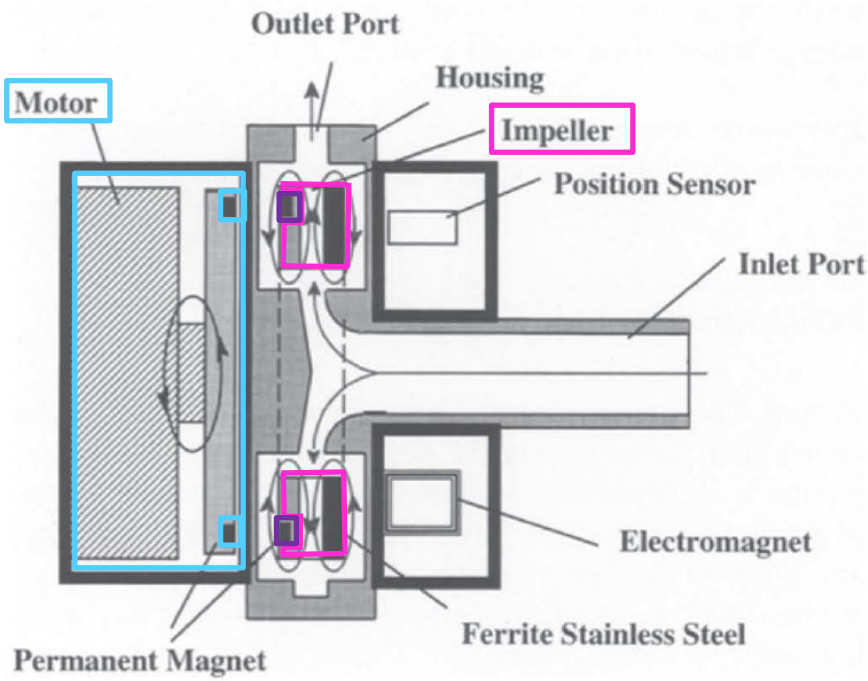


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

726. Accordingly, Akamatsu-1999 discloses "*the **second magnetic device*** ("DC brushless motor") *being positioned axially spaced apart from the guide surfaces of the **rotor*** ("impeller")."

xi. [1J] a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly

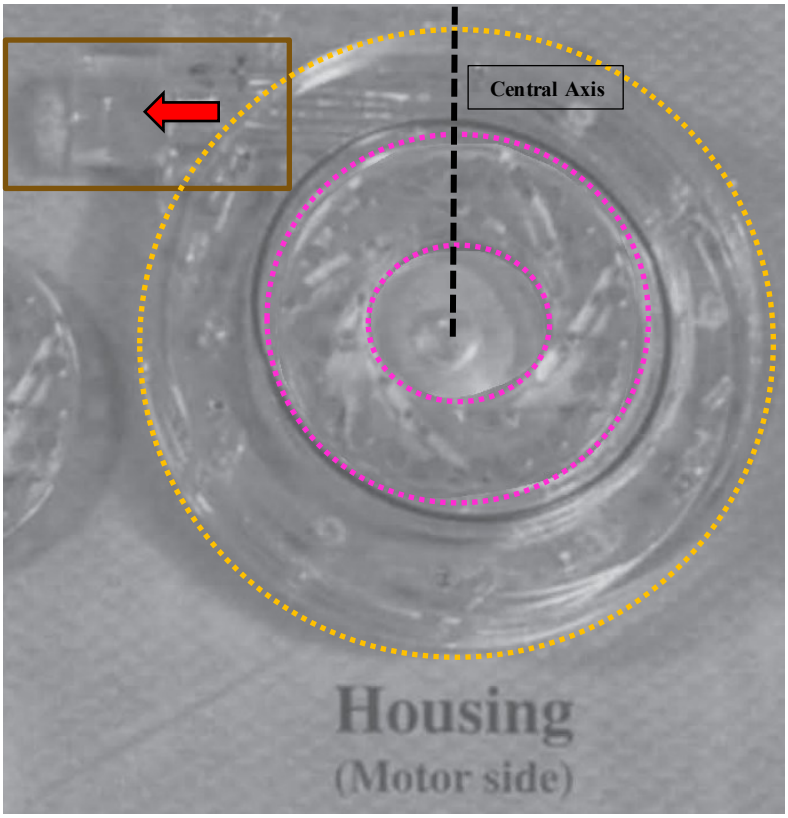
727. Akamatsu-1999 discloses "*a **blood outflow port** positioned radially adjacent the guide surfaces of the **rotor** such that, when the blood is driven by the*

magnetically driven rotor assembly, *the blood exits the* ***surrounding stationary housing*** *in a direction substantially perpendicular to the* ***central axis*** *of the* ***magnetically driven rotor assembly***."

728. As discussed with respect to element [1E], Akamatsu-1999 discloses that the T-ILVAS includes an "outflow conduit" or "outlet port." Ex.1006 at 4, Fig. 1, 2, 3; *see also* Ex.1006 at 4 ("The Dacron outflow graft…was sutured to the descending aorta …). I note that in parallel litigation, the Patent Owner has asserted that the blood outflow port of the "HeartMate 3" is "radially adjacent" to a magnetically driven rotor in the same way as described above in Akamatsu-1999. *See* Ex.1019, (Complaint, Ex. 13). For the purposes of my analysis, I also map the limitation that the **blood outflow port** (e.g., "outflow conduit") is "radially adjacent" to the **magnetically driven rotor assembly** (e.g., the "impeller" and "permanent magnets") in the same way.

729. Figure 5 (annotated) illustrates a top view of the motor side of the housing (**orange**) of the centrifugal pump, which shows the "outlet port" or "outflow conduit" (**brown**) being radially adjacent to the impeller:[20]

[20] Note that for purposes of this analysis, the impeller in Figure 5 has been superimposed over the motor side of the housing for illustrative purposes to show how the impeller would be configured in operation.



Ex.1006, Fig. 5 (annotated and altered).

730. I note that Figure 5 shows that when viewed from the top, the direction of the outlet port is offset from the axis of the inlet port as it does not intersect that axis. However, when viewed from the side, as shown in the cross-sectional view of Figure 2 (see below), the blood flows through the outlet port in a direction perpendicular from the inlet port. Therefore, a POSITA would understand that blood is driven through the outlet port in a direction that is "substantially perpendicular" to the inlet port and the central axis of the impeller, as recited in Claim 1.

731. Further, as discussed in [1K] below, the blood exits the housing when it is driven by the impeller and permanent magnet assembly to do so.

732. Thus, the **blood outflow port** (e.g., "outlet port" or "outflow conduit") is radially adjacent to the **magnetically driven rotor assembly** (e.g., "impeller" and "permanent magnets") such that blood driven by the impeller 19 is configured to exit the **surrounding stationary housing** (e.g., "housing") in a direction substantially perpendicular to the **central axis** of the impeller.

733. As another example, Figure 2 (annotated) illustrates a cross-sectional view of the centrifugal pump where the outlet port (**brown**) is radially adjacent to the impeller (**pink**) such that blood is driven (**red** arrows) by the impeller to exit the housing (**orange**) in a direction substantially perpendicular from the inlet port (**green**) and the central axis (**black**) of the impeller:

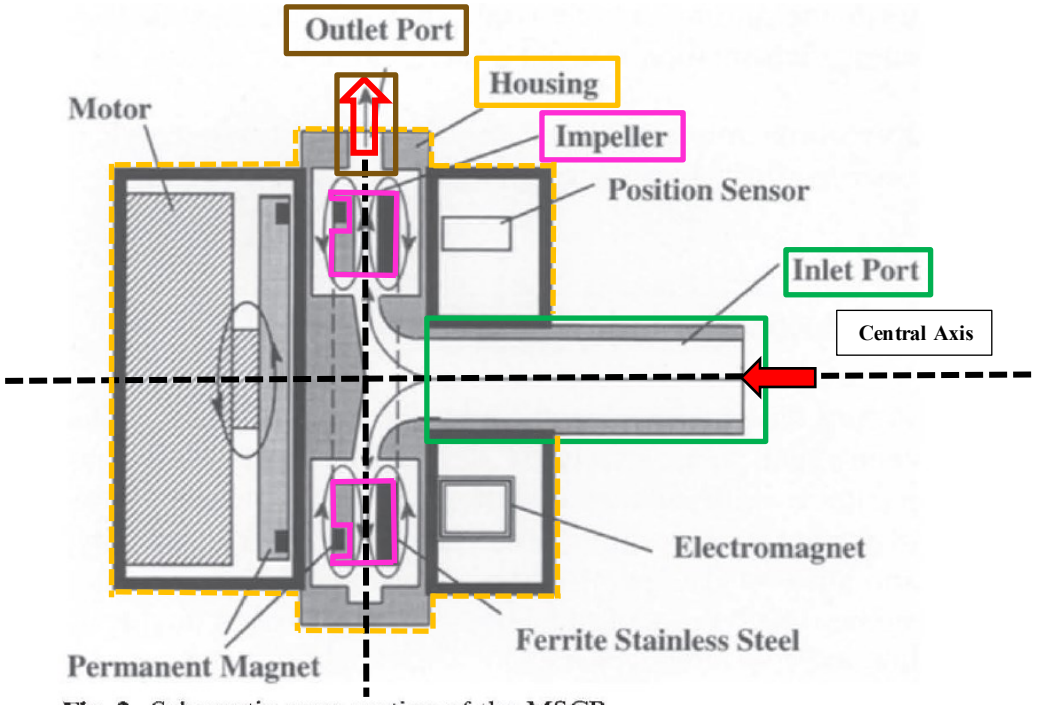


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

734. Another view of the outlet port (**brown**) and inlet port (**green**) is shown in Figure 3, which illustrates a side view of the centrifugal pump:

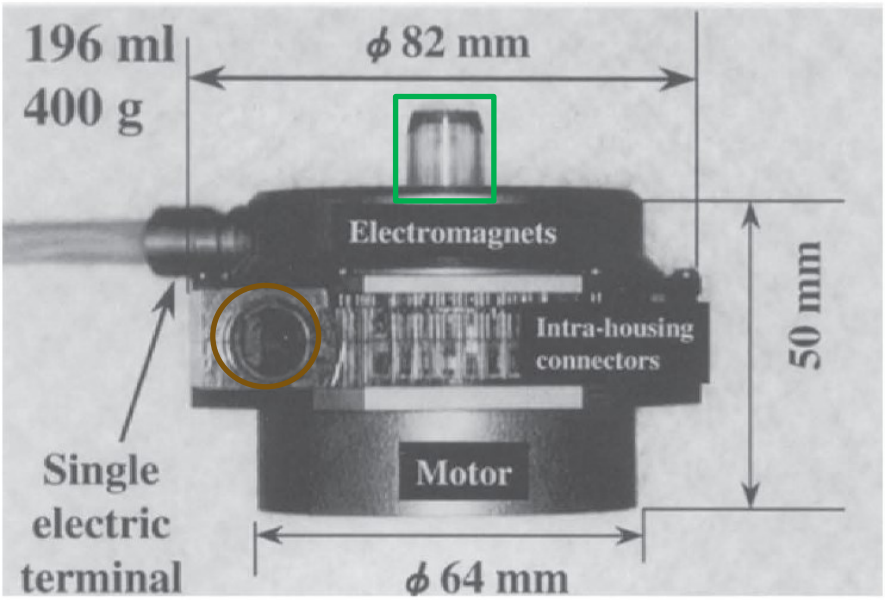


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3 (annotated).

735. Again, I note that Figure 3 shows that when viewed from this rotated side view, the axis of the outlet port is perpendicular to and offset from the axis of the inlet port. When viewed from the cross-sectional view of Figure 2 (see above), the blood flows through the outlet port in a direction perpendicular from the inlet port. Therefore, a POSITA would understand that blood is driven through the outlet port in a direction that is "substantially perpendicular" to the inlet port and the central axis of the impeller, as recited in Claim 1.

736. Accordingly, Akamatsu-1999 discloses that "*a* ***blood outflow port*** ("outlet port") *positioned radially adjacent the guide surfaces of the* ***rotor*** ("impeller") *such that, when the blood is driven by the* ***magnetically driven rotor***

assembly ("impeller" and "permanent magnets"), *the blood exits the* ***surrounding stationary housing*** ("housing") *in a direction substantially perpendicular to the* ***central axis*** *of the* ***magnetically driven rotor assembly***."

xii. [1K] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and

737. Akamatsu-1999 discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** *and orient the* ***magnetically driven rotor assembly*** *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***surrounding stationary housing*** *by the gap sized for passage of the blood*."

738. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the gap sized for passage of the blood**" to mean that the "blood flowing" "in response to rotation of the magnetically driven rotor" ***causes*** the "magnetically driven rotor" to remain "entirely spaced apart from the surrounding stationary housing." *See* Section

VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "the magnetically driven rotor remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood" to include not only hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

739. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [1G], Akamatsu-1999 discloses a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). For example, Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor." Ex.1006, [0072]. Figure 2 shows that the T-ILVAS achieves this "contact-free" rotation of the impeller because the "DC brushless motor" rotates a plate having a "permanent magnet," which creates a torque on the impeller because of the attractive magnetic force (or "magnetic coupling") between the permanent magnet within the motor and the permanent magnet within the impeller. Ex.1006 at 4, Fig. 2. That is, the rotation of the impeller is locked against relative rotation of the motor plate.

740. Therefore, the DC brushless motor is configured to orient the impeller to rotate within the housing via the magneto coupling. Akamatsu-1999 discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear." Ex.1006 at 6.

741. Akamatsu-1999 discloses that the impeller "is suspended magnetically by the three electromagnets" which comprise the "magnetic bearing." Ex.1006 at 4. "The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing ***contact-free rotation*** of the impeller without any material wear it is expected to be one of the most durable blood pumps."). The V-ILVAS Model II used during testing "had a single electric wire, with the intrahousing connectors between the motor and the electromagnets." Thus, in response to the rotation of the impeller

by motor via the magneto coupling, the impeller remains spaced apart from the housing using the electromagnets, which interact with the "ferrite stainless steel" portion of the impeller, as shown in Figure 2.

742. For example, Figure 2 (annotated) illustrates that the magneto coupling orients the impeller (**pink**) such that in response to the rotation of the impeller (shown by the circular arrows surrounding the shaft of the motor driving the plate holding the permanent magnets), the impeller remains spaced apart from the housing (**orange**) by the blood flowing (**red** arrows) from the inlet port (**green**) to the outlet port (**brown**) using the electromagnets which interact with the "ferrite stainless steel" portion of the impeller:

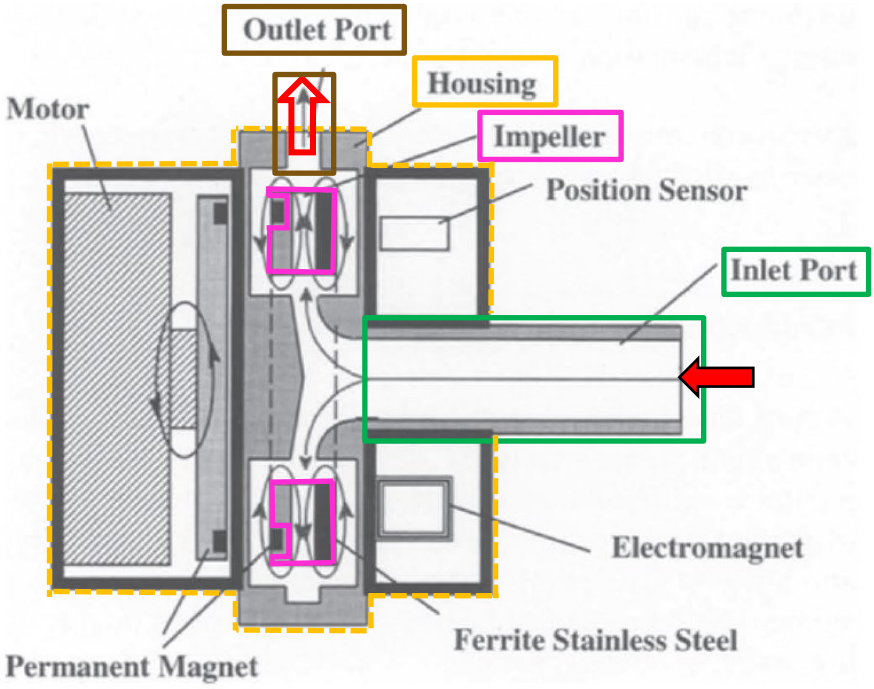


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

743. Accordingly, Akamatsu-1999 discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** ("impeller" and "permanent magnets") *and orient the* ***magnetically driven rotor assembly*** *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***surrounding stationary housing*** ("housing") *by the gap sized for passage of the blood*."

xiii. [1L] an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output,

744. Akamatsu-1999 discloses "*an* ***external control unit*** *configured to regulate operation of the* ***second magnetic device*** *based upon a control value indicative of cardiac output*."

745. For example, Akamatsu-1999 discloses a "controller" (shown to be externally worn in Figure 1) used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump via electric wires. Ex.1006 at 3, 4. The "Model I" and the "modified Model II" had "dual electric wires separately connect to the motor and electromagnets," while the "Model II" version of the T-ILVAS "had a single electric wire, with the intrahousing connectors

between the motor and the electromagnets." Ex.1006 at 4. Akamatsu-1999 further discloses that during testing, "[t]he pump was operated at a fixed rotational speed" and "***[t]he pump was percutaneously driven***," i.e., via the electric wire through the skin. Ex.1006 at 4, 5. In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5.

746. Thus, the "controller" disclosed in Akamatsu-1999 is an **external control unit** as recited in Claim 1 which regulates operation of the **second magnetic device** (e.g., "DC brushless motor," Ex.1006 at 3, 4).

747. The configuration of the external control unit's connection (**lime green**) via an electric wire to the centrifugal pump to control the DC brushless motor (**light blue**) is shown in Figure 3 (annotated):

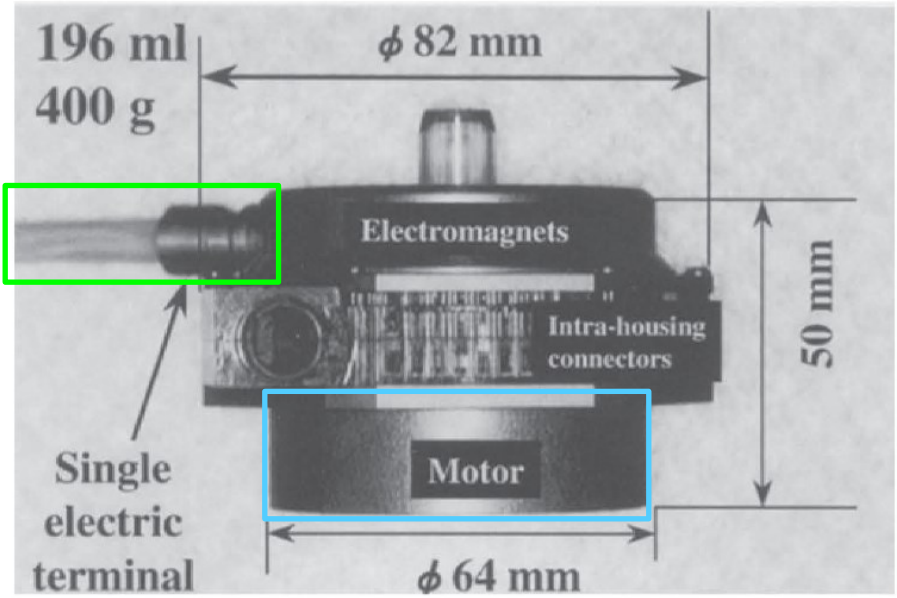


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3 (annotated).

748. Figure 1 (annotated) also illustrates the connection of the external controller (**lime green**) to the centrifugal pump (**blue**), in which the DC brushless motor and the impeller are enclosed:

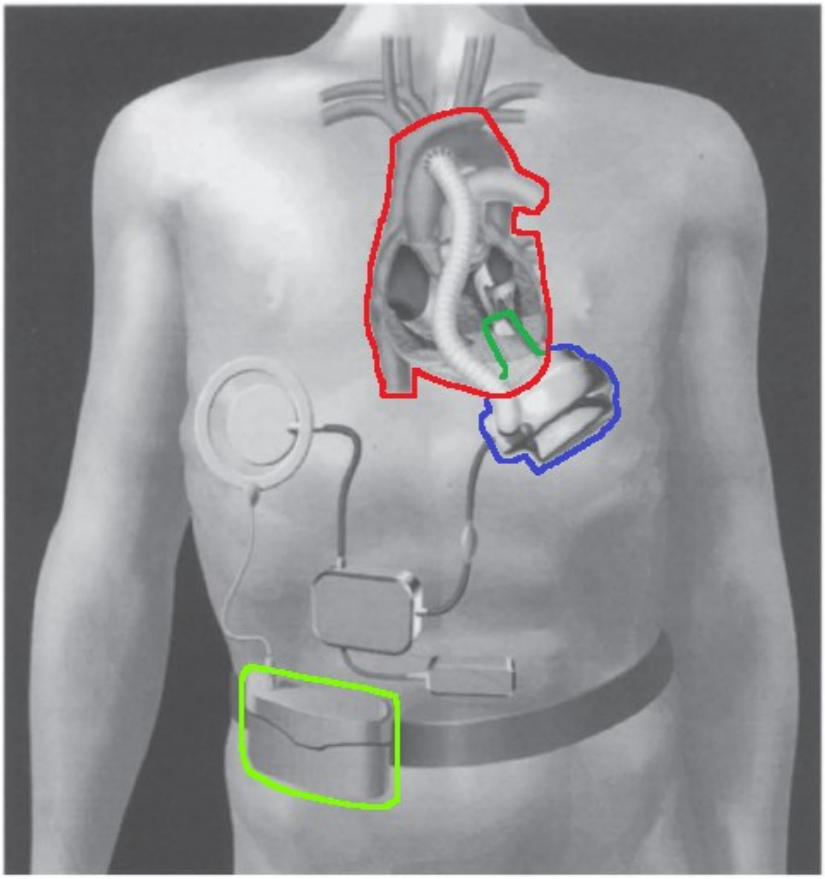


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

749. As discussed above, Akamatsu-1999 discloses an **external control unit** ("controller," shown to be externally worn in Figure 1) used to provide "electric

current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump via electric wires. Ex.1006 at 3, 4; *see supra* Section X.C.1.xiii.

750. The 077 Patent does not define "a control value indicative of cardiac output." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 external control unit is configured to control the operation of the second magnetic device using a control value, such as what Abbott calls a "fixed speed" or "lower speed limit" which is indicative of cardiac output (e.g. output as measured in liters of blood per minute. *See, e.g.*, Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "a control value indicative of cardiac output."

751. Accordingly, Akamatsu-1999 further discloses that during testing, "[t]he pump was operated at a fixed rotational speed" and "[t]he pump was percutaneously driven," i.e., via the electric wire through the skin. Ex.1006 at 4, 5. In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5.

752. Thus, the "controller" disclosed in Akamatsu-1999 is an **external control unit** as recited in Claim 1 that controls the **second magnetic device** (e.g., "DC brushless motor," Ex.1006 at 3, 4) in response to measurement values indicative of cardiac output of the heart (e.g., "continuously measur[ing]" "aortic

pressure and pump flow rate" and operating the pump at a "fixed rotational speed," Ex.1006 at 4, 5).

753. Accordingly, Akamatsu-1999 discloses "*an* ***external control unit*** ("controller") *configured to regulate operation of the* ***second magnetic device*** ("DC brushless motor") *based upon a control value indicative of cardiac output*."

xiv. [1M] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,

754. Akamatsu-1999 discloses that "*the* ***external control unit*** *is connectable to the* ***heart assist pump device*** *for controlling the* ***second magnetic device*** *to thereby magnetically drive the rotation of the* ***magnetically driven rotor assembly*** *via the magneto coupling with the* ***first magnetic device***."

755. As discussed with respect to element [1L], Akamatsu-1999 discloses an **external control unit** ("controller," shown to be externally worn in Figure 1) used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump via electric wires. Ex.1006 at 3, 4; *see supra* Section X.C.1.xiii to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** (e.g., "impeller" and "permanent magnets"

Ex.1006 at 3, 4) via the magneto coupling with the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). *See supra* Sections X.C.1.viii and X.C.1.xii.

756. The configuration of the external control unit's connection (**lime green**) via an electric wire to the centrifugal pump to control the DC brushless motor (**light blue**) is shown in Figure 3 (annotated):

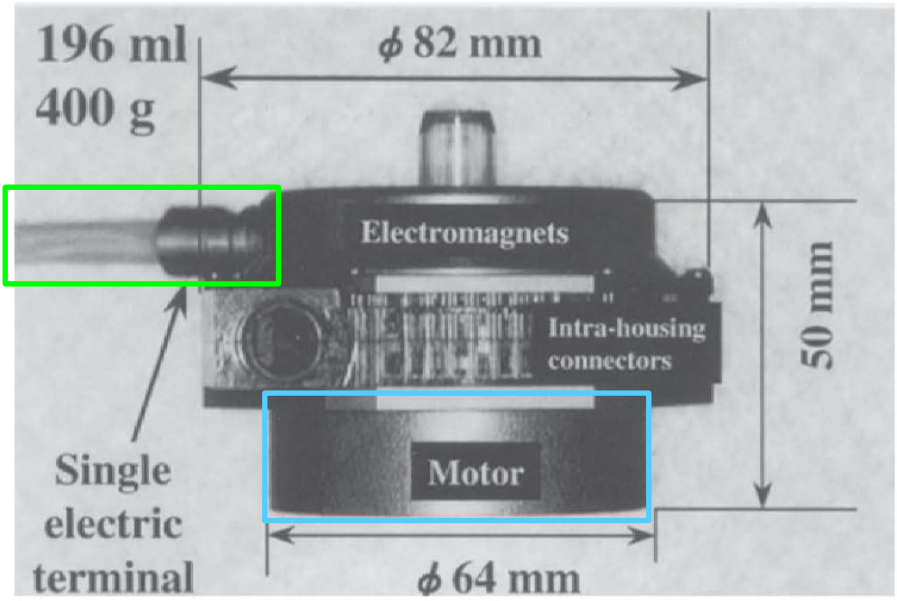


Fig. 3. Implantable Model II MSCP with intrahousing connectors

Ex.1006, Fig. 3 (annotated).

757. Figure 1 (annotated) also illustrates the connection of the external controller (**lime green**) to the centrifugal pump (**blue**), in which the DC brushless motor and the impeller are enclosed:

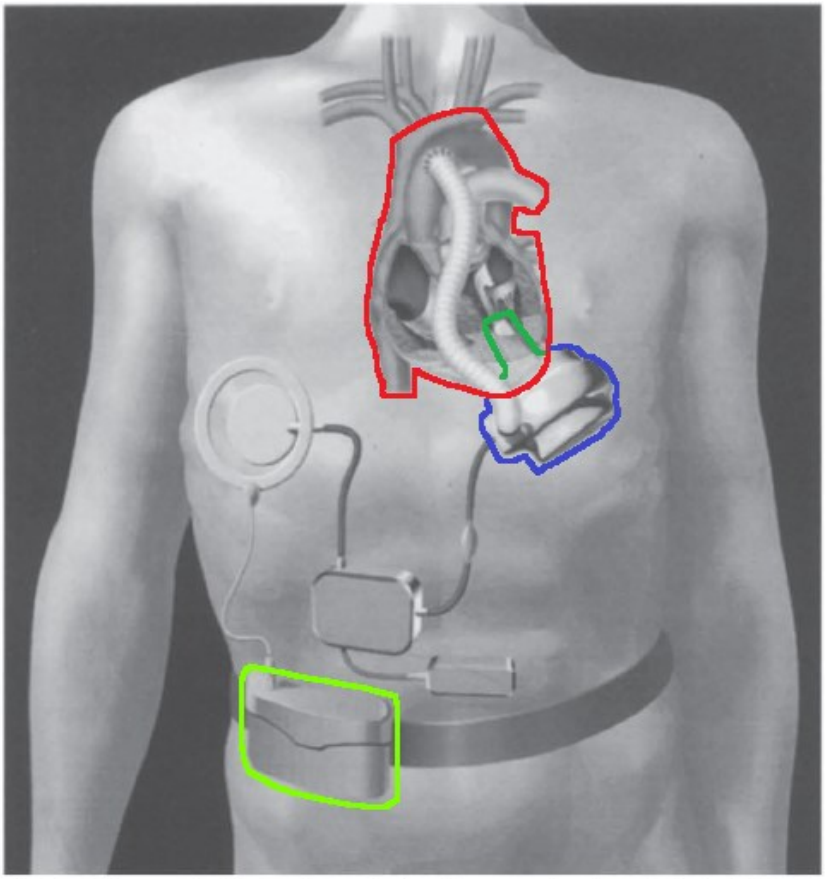


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

758. Accordingly, Akamatsu-1999 discloses that "*the* ***external control unit*** ("controller") *is connectable to the* ***heart assist pump device*** ("centrifugal pump") *for controlling the* ***second magnetic device*** ("DC brushless motor") *to thereby magnetically drive the rotation of the* ***magnetically driven rotor assembly*** ("impeller" and "permanent magnets") *via the magneto coupling with the* ***first magnetic device*** (impeller's "permanent magnet")."

2. Claims 2, 3, and 4

759. Claim 4 depends from dependent claim 3 which depends from dependent Claim 2 which depends from independent Claim 1. Accordingly, I address each dependent claim in turn.

a. [2] The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.

760. Akamatsu-1999 discloses and/or renders obvious claim 2. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 2.

761. Akamatsu-1999 discloses that "*the **first magnetic device** is configured to be positioned between the **second magnetic device** and the guide surfaces of the **rotor** of the **magnetically driven rotor assembly**.*"

762. As discussed with respect to element [1G], Akamatsu-1999 describes a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2), which drives rotation of the **magnetically driven rotor** (e.g., "impeller"). *See supra* Section X.C.1.viii. For example, Akamatsu-1999 discloses that the "impeller rotates by a ***magnetic coupling*** between the impeller and the motor." Ex.1006, [0072].

763. Thus, the "permanent magnets" imbedded within the impeller are necessarily between the "DC brushless motor" and the "impeller" in order for the motor to drive the impeller's motion. Figure 2 (annotated) illustrates that the permanent magnets (**purple**) of the impeller are positioned between the DC brushless motor (**light blue**) and the impeller (**pink**) in order to drive rotation via the magneto coupling:

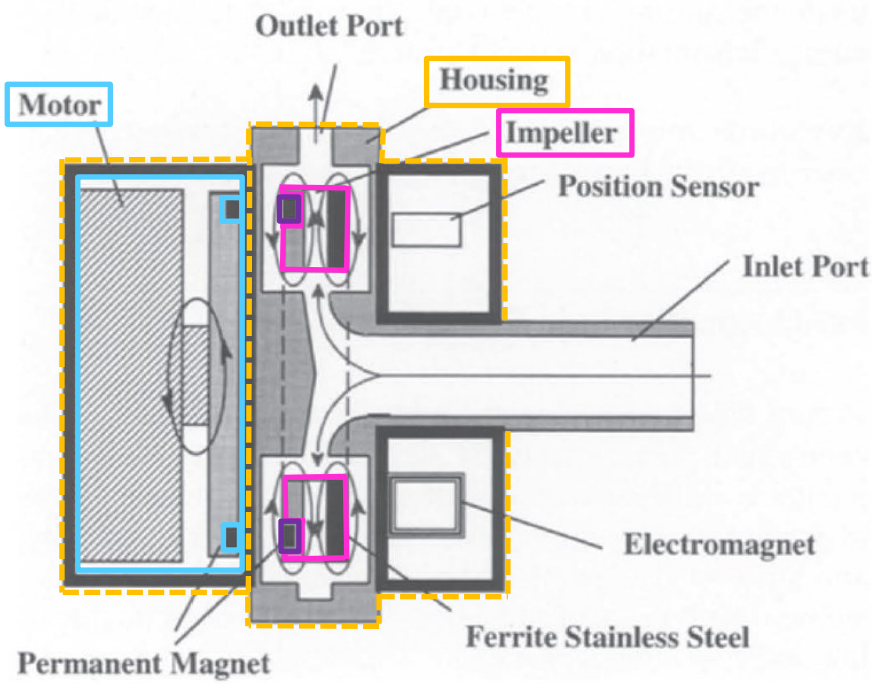


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

764. Accordingly, Akamatsu-1999 discloses that "*the **first magnetic device*** ("permanent magnet") *is configured to be positioned between the **second magnetic***

device ("DC brushless motor") *and the guide surfaces of the* ***rotor*** ("impeller") *of the* ***magnetically driven rotor assembly***."

b. [3] The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.

765. Akamatsu-1999 discloses and/or renders obvious claim 3. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claims 1 and 2. I incorporate that discussion into my analysis for claim 3.

766. Akamatsu-1999 discloses that "*the* ***first magnetic device*** *is configured to rotate together with the* ***rotor*** *relative to the* ***surrounding stationary housing***."

767. As discussed with respect to element [1C], Figure 2 illustrates that the impeller has a "permanent magnet" located within it, and therefore the "permanent magnet" located within the impeller is a **first magnetic device** which is rigidly coupled to the **magnetically driven rotor**. Ex.1006, Fig. 2. *See supra* Section X.C.1.iv.

768. For the same reasons, because the "permanent magnets" are rigidly coupled to the "impeller," the "permanent magnets" rotate together with the "impeller" relative to and within the housing providing "contact-free rotation." Ex.1006 at 4, 6.

769. Accordingly, Akamatsu-1999 discloses that "*the **first magnetic device*** ("permanent magnet") *is configured to rotate together with the **rotor*** ("impeller") *relative to the **surrounding stationary housing*** ("housing")."

c. [4] The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.

770. Akamatsu-1999 discloses and/or renders obvious claim 4. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claims 1, 2, and 3. I incorporate that discussion into my analysis for claim 4.

771. Akamatsu-1999 discloses that "*the **second magnetic device** is positioned closer to the **blood outflow port** than to the suction end of the **inflow tube***."

772. For example, Figure 2 (annotated) illustrates that the DC brushless motor (**light blue**) is positioned closer to the outlet port 14 (**brown**) than the DC brushless motor is positioned relative to the suction end of the inlet port (**green**):

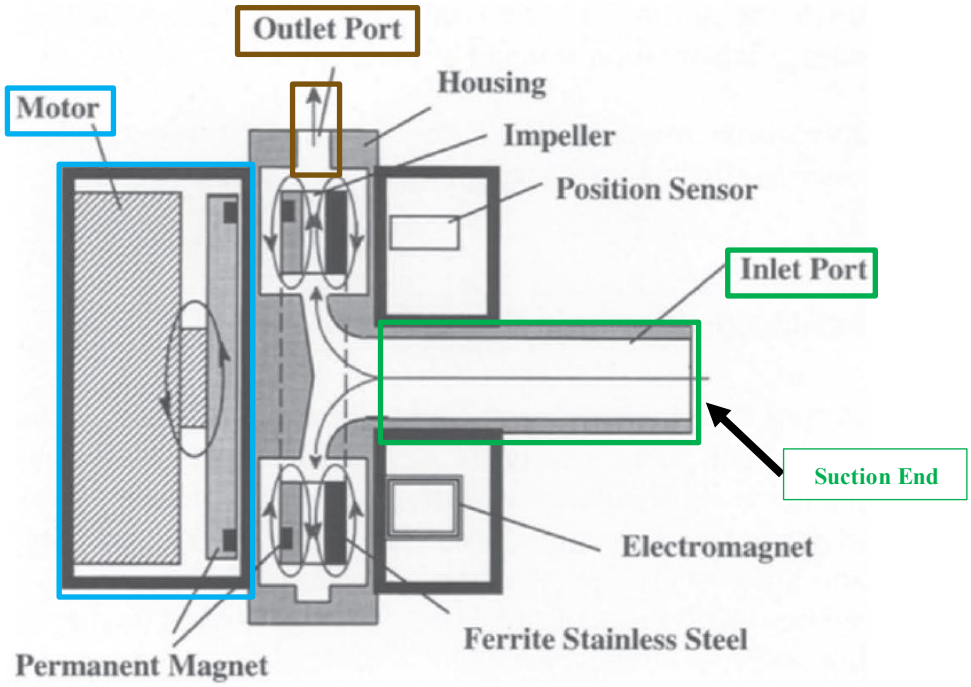


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

773. Accordingly, Akamatsu-1999 discloses that "*the* ***second magnetic device*** ("DC brushless motor") *is positioned closer to the* ***blood outflow port*** ("outlet port") *than to the suction end of the* ***inflow tube*** ("inlet port")."

3. Claim 5

a. [5] The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.

774. Akamatsu-1999 discloses claim 5. I have already explained how Akamatsu-1999 discloses each and every element of claim 1. I incorporate that discussion into my analysis for claim 5.

775. Akamatsu-1999 discloses that "*the **magnetically driven rotor assembly** is sealed from the **second magnetic device** and a drive source configured to regulate the operation of the **second magnetic device**.*"

776. As discussed with respect to [1H], the **impeller** and **permanent magnet** are sealed from the **DC brushless motor**.

777. Further, as discussed with respect to elements [1L] and [1M], Akamatsu-1999 discloses a "controller" used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump. Ex.1006 at 3, 4. Akamatsu-1999 further discloses that during testing, "[t]he pump was percutaneously driven," i.e., via the electric wire through the skin. Ex.1006 at 4, 5.

778. Accordingly, Akamatsu-1999 discloses that "*the **magnetically driven rotor assembly*** ("impeller" and "permanent magnet") *is sealed from the **second***

magnetic device ("DC brushless motor") *and a drive source configured to regulate the operation of the* ***second magnetic device***."

4. Claim 7

a. [7] The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

779. Akamatsu-1999 discloses and/or renders obvious claim 7. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 7.

780. Akamatsu-1999 discloses "*one or more sensors configured to deliver feedback signals to the* ***external control unit***."

781. As discussed with respect to elements [1L]-[1M], Akamatsu-1999 discloses a "controller" used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump. Ex.1006 at 3, 4. Akamatsu-1999 further discloses that "[t]he electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4. Akamatsu-1999 therefore discloses that the "three position sensors" provide feedback signals to the **external control unit** (e.g., the "controller, Ex.1006 at 3, 4) in order to control the electric current provided to the motor.

782. Accordingly, Akamatsu-1999 discloses "*one or more sensors* ("position sensors") *configured to deliver feedback signals to the* ***external control unit*** ("controller")."

5. Claim 10

a. [10] The system of claim 1, wherein the heart assist pump device is a catheter device.

783. Akamatsu-1999 discloses and/or renders obvious claim 10. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 10.

784. Akamatsu-1999 discloses that "*the* ***heart assist pump device*** *is a catheter device*."

785. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See*, e.g., Ex.1019, Complaint, Ex. 13. For the purposes of my analysis, I adopt that construction of "catheter device."

786. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], the centrifugal pump disclosed in Akamatsu-1999

includes a "catheter" which is an **inflow tube** (e.g., "inflow conduit" or "inlet port," Ex.1006 at 4) that is "inserted into the left ventricle through a cuff sutured to the left ventricular apex." Ex.1006 at 4. Therefore, the centrifugal pump disclosed in Akamatsu-1999 is a catheter device.

787. Accordingly, Akamatsu-1999 discloses that "*the **heart assist pump device*** ("centrifugal pump") *is a catheter device*."

6. Claim 16

788. As demonstrated below, the scope of claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. For instance, the "surrounding stationary housing" of claim 1 is essentially the same as the "chamber walls at least partially defining a chamber" of claim 16. Similarly, because the "inflow tube" and "central axis" of claim 1 are aligned, the claimed "inflow axis" of claim 16 is rendered obvious for the same reasons.

a. [16pre] A system for assisting blood circulation of a heart, the system comprising

789. Akamatsu-1999 discloses "*a system for assisting blood circulation of a **heart***."

790. This element is invalid for the same reasons discussed above in [1PRE], thus, I incorporate that discussion into my analysis here.

791. Accordingly, Akamatsu-1999 discloses "a system for assisting blood circulation of a **heart**."

b. [16a] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;

792. Akamatsu-1999 discloses "*a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**.*"

793. This element is invalid for the same reasons discussed above in [1A] and [1B], thus, I incorporate that discussion into my analysis here.

794. Accordingly, Akamatsu-1999 discloses "a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**."

c. [16b] chamber walls at least partially defining a chamber to receive blood from the inflow tube;

795. Akamatsu-1999 discloses "*chamber walls at least partially defining a chamber to receive blood from the **inflow tube**.*"

796. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

797. Accordingly, Akamatsu-1999 discloses "***chamber walls at least partially defining a chamber*** *to receive blood from the* ***inflow tube***."

d. [16c] a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device

798. Akamatsu-1999 discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

799. This element is invalid for the same reasons discussed above in [1B] and [1C], thus, I incorporate that discussion into my analysis here.

800. Accordingly, Akamatsu-1999 discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

e. [16d] that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor

801. Akamatsu-1999 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

802. This element is invalid for the same reasons discussed above in [1C], thus, I incorporate that discussion into my analysis here.

803. Accordingly, Akamatsu-1999 discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

f. [16e] [the rotor] having guide surfaces to produce centrifugal flow components,

804. Akamatsu-1999 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

805. This element is invalid for the same reasons discussed above in [1D], thus, I incorporate that discussion into my analysis here.

806. Accordingly, Akamatsu-1999 discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

g. [16f] the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation

807. Akamatsu-1999 discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

808. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

809. Accordingly, Akamatsu-1999 discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

h. [16g] [the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;

810. Akamatsu-1999 discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

811. This element is invalid for the same reasons discussed above in [1B] and [1E], thus, I incorporate that discussion into my analysis here.

812. Accordingly, Akamatsu-1999 discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

i. [16h] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

813. Akamatsu-1999 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

814. This element is invalid for the same reasons discussed above in [1G], thus, I incorporate that discussion into my analysis here. Additionally, Akamatsu-1999 discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor (the '***second magnetic device***')," and thus, Akamatsu-1999 discloses a "*magnetic drive system*." Ex. 1006, 4.

815. Accordingly, Akamatsu-1999 discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

j. [16i] the second magnetic device positioned axially closer to the first magnetic device than to the rotor of the magnetically driven rotor assembly so as to magnetically drive rotation of the magnetically driven rotor assembly within the chamber via a magneto coupling with the first magnetic device; and

816. Bourque-2001 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device***."

817. This element is invalid for the same reasons discussed above in [1K] and [2], thus, I incorporate that discussion into my analysis here.

818. Accordingly, Bourque-2001 discloses "*the **magnetic drive system** positioned axially closer to the **first magnetic device** than to the rotor of the **magnetically driven rotor assembly** so as to magnetically drive rotation of the **magnetically driven rotor assembly** within the **chamber** via a magneto coupling with the **first magnetic device***."

k. [16j] and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,

819. Akamatsu-1999 discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

820. This element is invalid for the same reasons discussed above in [1H], thus, I incorporate that discussion into my analysis here.

821. Accordingly, Akamatsu-1999 discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

l. [16k] a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,

822. Akamatsu-1999 discloses "*a **blood outflow port** positioned radially outward of the guide surfaces of the **rotor** such that, when the blood is driven by*

*the **magnetically driven rotor assembly**, the blood exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

823. This element is invalid for the same reasons discussed above in [1J] thus, I incorporate that discussion into my analysis here.

824. Accordingly, Akamatsu-1999 discloses "*a **blood outflow port** positioned radially outward of the guide surfaces of the **rotor** such that, when the blood is driven by the **magnetically driven rotor assembly**, the blood exits the **chamber** in a direction substantially perpendicular to the **inflow axis**.*"

m. [16l] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and

825. Akamatsu-1999 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

826. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

827. Accordingly, Akamatsu-1999 discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

n. [16m] an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output

828. Akamatsu-1999 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

829. This element is invalid for the same reasons discussed above in [1L], thus, I incorporate that discussion into my analysis here.

830. Accordingly, Akamatsu-1999 discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

o. [16n] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

831. Akamatsu-1999 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

832. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

833. Accordingly, Akamatsu-1999 discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

7. Claim 17

834. Claim 17, depends from independent Claim 16. Accordingly, I address this dependent claim herein.

a. [17] The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.

835. Akamatsu-1999 discloses and/or renders obvious claim 17. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 17.

836. Akamatsu-1999 discloses that "*the **first magnetic device** is rigidly coupled to the **rotor** of the **magnetically driven rotor assembly** at a position between the **second magnetic device** and the **rotor**.*"

837. As discussed with respect to element [1G], Akamatsu-1999 describes a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2), which drives rotation of the **magnetically driven rotor** (e.g., "impeller"). *See supra* Section X.C.1.viii. For example, Akamatsu-1999 discloses that the "impeller rotates by a ***magnetic coupling*** between the impeller and the motor." Ex.1006, [0072].

838. Thus, the "permanent magnets" imbedded within the impeller are necessarily between the "DC brushless motor" and the "impeller" in order for the

motor to drive the impeller's motion. Figure 2 (annotated) illustrates that the permanent magnets (**purple**) of the impeller are positioned between the DC brushless motor (**light blue**) and the impeller (**pink**) in order to drive rotation via the magneto coupling:

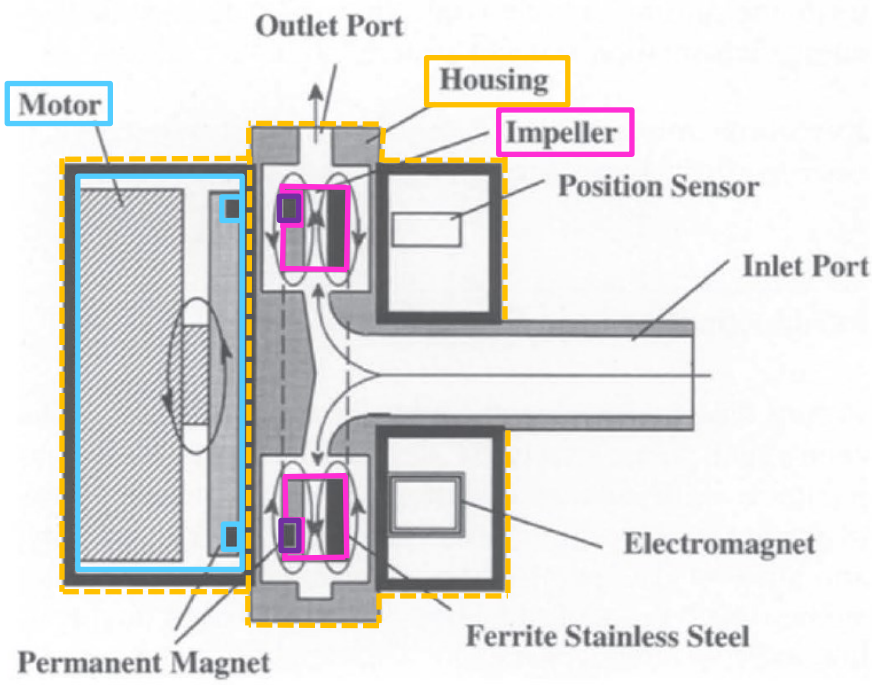


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

839. Accordingly, Akamatsu-1999 discloses that "*the **first magnetic device*** ("permanent magnet") *is rigidly coupled to the **rotor*** ("impeller") *of the **magnetically driven rotor assembly** at a position between the **second magnetic device*** ("DC brushless motor") *and the **rotor**.*"

8. Claims 18, 19, 20, and 21

840. Claim 19, depends from dependent Claim 18. Accordingly, I address this dependent claim herein.

a. [18] The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.

841. Akamatsu-1999 discloses and/or renders obvious claim 18. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 18.

842. Akamatsu-1999 discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor assembly***."

843. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the gap sized for passage of the blood**" to mean that the "blood flowing" "in response to rotation of the magnetically driven rotor" ***causes*** the "magnetically driven rotor" to remain

"entirely spaced apart from the surrounding stationary housing." *See* Section VII.A.2. However while I disagree, for the purposes of my analysis in this Ground, I assume that the Patent Owner's apparent broader construction (in parallel litigation) of "the magnetically driven rotor remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood" to include not only hydrodynamic suspension of the rotor but also that it may be met by *exclusively* magnetic suspension, is correct. *See* Ex.1019.

844. Accordingly, based on the Patent Owner's understanding of the term and as discussed with respect to element [1G], Akamatsu-1999 discloses a magneto coupling between the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2). For example, Akamatsu-1999 discloses that the "impeller rotates by a magnetic coupling between the impeller and the motor." Ex.1006, [0072]. Figure 2 shows that the T-ILVAS achieves this "contact-free" rotation of the impeller because the "DC brushless motor" rotates a plate having a "permanent magnet," which creates a torque on the impeller because of the attractive magnetic force (or "magnetic coupling") between the permanent magnet within the motor and the permanent magnet within the

impeller. Ex.1006 at 4, Fig. 2. That is, the rotation of the impeller is locked against relative rotation of the motor plate.

845. Therefore, the DC brushless motor is configured to orient the impeller to rotate within the housing via the magneto coupling. Akamatsu-1999 discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any material wear." Ex.1006 at 6.

846. Akamatsu-1999 discloses that the impeller "is suspended magnetically by the three electromagnets" which comprise the "magnetic bearing." Ex.1006 at 4. "The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also* Ex.1006 at 3 ("Because the MSCP is a sealless rotary pump providing ***contact-free rotation*** of the impeller without any material wear it is expected to be one of the most durable blood pumps."). The V-ILVAS Model II used

during testing "had a single electric wire, with the intrahousing connectors between the motor and the electromagnets." Thus, in response to the rotation of the impeller by motor via the magneto coupling, the impeller remains spaced apart from the housing using the electromagnets, which interact with the "ferrite stainless steel" portion of the impeller, as shown in Figure 2.

847. For example, Figure 2 (annotated) illustrates that the magneto coupling orients the impeller (**pink**) such that in response to the rotation of the impeller (shown by the circular arrows surrounding the shaft of the motor driving the plate holding the permanent magnets), the impeller remains spaced apart from the housing (**orange**) by the blood flowing (**red** arrows) from the inlet port (**green**) to the outlet port (**brown**) using the electromagnets which interact with the "ferrite stainless steel" portion of the impeller:

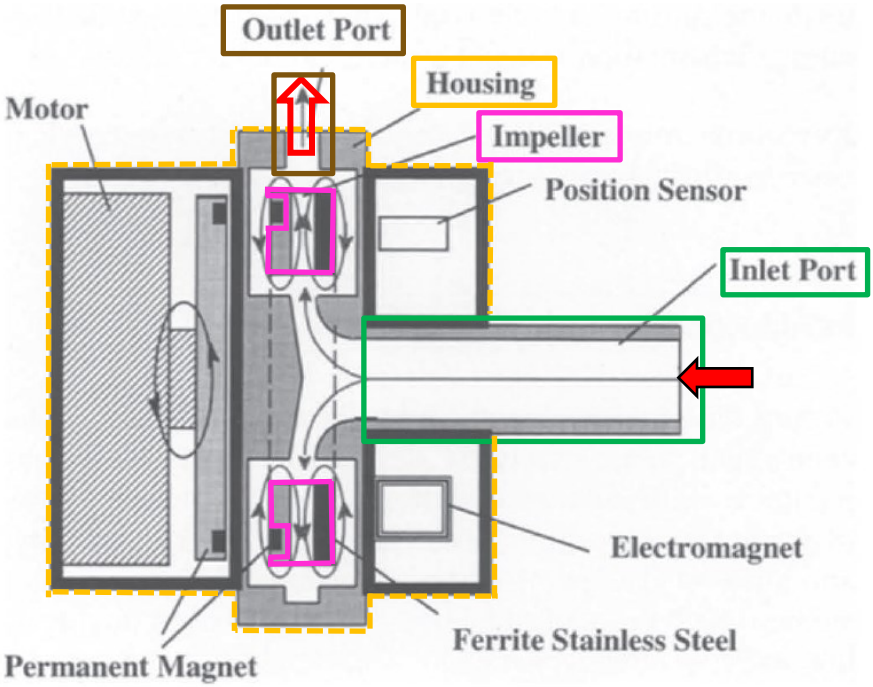


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

848. Accordingly, Akamatsu-1999 discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the* ***second magnetic device*** *drives rotation of the* ***magnetically driven rotor assembly*** ("impeller")."

b. [19] The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.

849. Akamatsu-1999 discloses claim 19. I have already explained how Akamatsu-1999 discloses each and every element of claim 18. I incorporate that discussion into my analysis for claim 19.

850. Akamatsu-1999 discloses that "*the gap surrounds the **magnetically driven rotor assembly***."

851. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

852. Accordingly, Akamatsu-1999 discloses that "*the gap surrounds the **magnetically driven rotor assembly***."

c. [20] The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.

853. Akamatsu-1999 discloses claim 20. I have already explained how Akamatsu-1999 discloses each and every element of claims 18 and 19. I incorporate that discussion into my analysis for claim 20.

854. Akamatsu-1999 discloses that "*at least part of the gap extends radially outward from the **magnetically driven rotor assembly***."

855. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

856. Accordingly, Akamatsu-1999 discloses that "*at least part of the gap extends radially outward from the **magnetically driven rotor assembly***."

d. [21] The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.

857. Akamatsu-1999 discloses claim 21. I have already explained how Akamatsu-1999 discloses each and every element of claims 18, 19, and 20. I incorporate that discussion into my analysis for claim 21.

858. Akamatsu-1999 discloses that "*at least part of the gap extends along a face of the **magnetically driven rotor assembly** that is axially opposite from the **inflow tube***."

859. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

860. Accordingly, Akamatsu-1999 discloses that "*at least part of the gap extends along a face of the **magnetically driven rotor assembly** that is axially opposite from the **inflow tube***."

9. Claims 22 and 23

861. Claim 23, depends from dependent Claim 22. Accordingly, I address this dependent claim herein.

a. [22] The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

862. Akamatsu-1999 discloses and/or renders obvious claim 22. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 22.

863. Akamatsu-1999 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly** is positioned, and the magnetic drive system is positioned within a **second chamber** sealed from the **first chamber**.*"

864. As discussed with respect to element [1G], Akamatsu-1999 describes a magneto coupling between the **second chamber** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) and the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2), which drives rotation of the **magnetically driven rotor assembly** (e.g., "impeller"). *See supra* Section X.C.1.viii. For example, Akamatsu-1999 discloses that the "impeller rotates by a ***magnetic coupling*** between the impeller and the motor." Ex.1006, [0072].

865. Thus, the "permanent magnets" imbedded within the impeller are necessarily between the "DC brushless motor" and the "impeller" in order for the

motor to drive the impeller's motion. Figure 2 (annotated) illustrates that the permanent magnets (**purple**) of the impeller are positioned between the DC brushless motor (**light blue**) and the impeller (**pink**) in order to drive rotation via the magneto coupling:

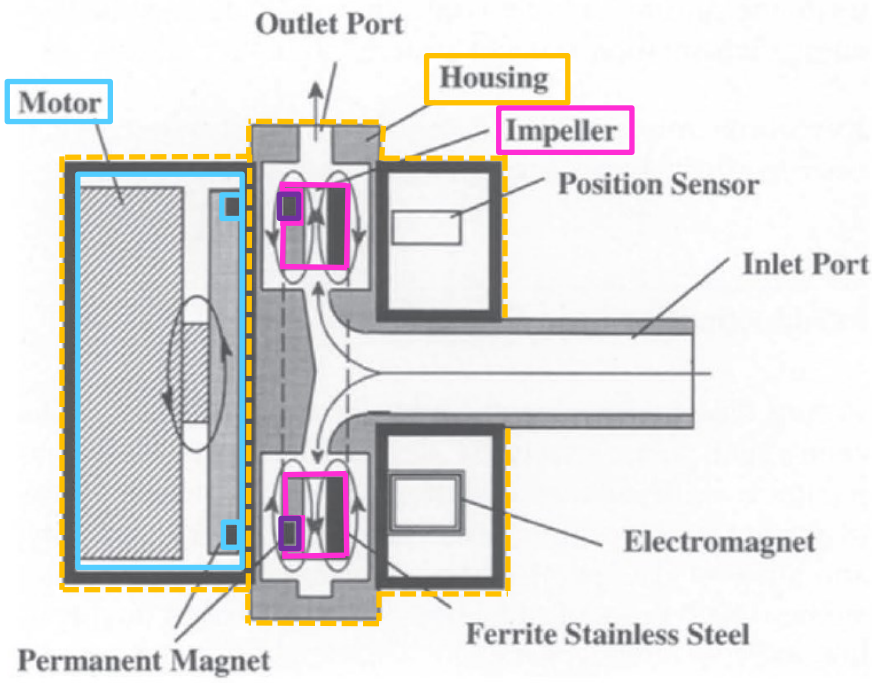


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

866. As discussed with respect to element [1E], Akamatsu-1999 discloses that the centrifugal pump includes an "impeller" and "housing." Ex.1006 at 5, Fig. 2; *see also* Ex.1006 at 5 ("The electric current of the electromagnet is controlled by using three position sensors to ***maintain the impeller free-floating at the center of the pump housing***."); *supra* Section X.C.1.vi. The "impeller" is a **magnetically**

driven rotor. *See supra* Section X.C.1.iii. And as discussed with respect to element [1C], the "permanent magnet" within the impeller is a **first chamber**. Ex.1006, [0070], [0064]; *supra* Section X.C.1.iv.

867. Akamatsu-1999 further discusses that "conventional rotary blood pumps have had limited durability and nonthrombogenicity because of problems associated with the bearings and seal." Ex.1006 at 6. As such, "the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump." Ex.1006 at 6. And accordingly, Akamatsu "developed a ***sealless centrifugal pump*** with a magnetically suspended impeller (MSCP), which operates completely ***contact-free*** without any material wear." Ex.1006 at 6. While Akamatsu-1999 reported a "leakage of blood into the electromagnets" during one study, that issue was resolved—"[t]he connector system of the Model II pump was changed to a dual-wired system"—to seal the electromagnets and from the pump housing.

868. Thus, the **second chamber** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2) is spaced apart and sealed from the **magnetically driven rotor assembly** (e.g., "impeller," Ex.1006 at 4, Fig. 2) and the

first magnetic device (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2).

869. Figure 2 (annotated) of Akamatsu-1999 illustrates a cross-sectional view of the centrifugal pump having a DC brushless motor (**light blue**) that is spaced apart and sealed from the impeller (**pink**), including a permanent magnet (**purple**), as indicated by the solid black line surrounding the motor:

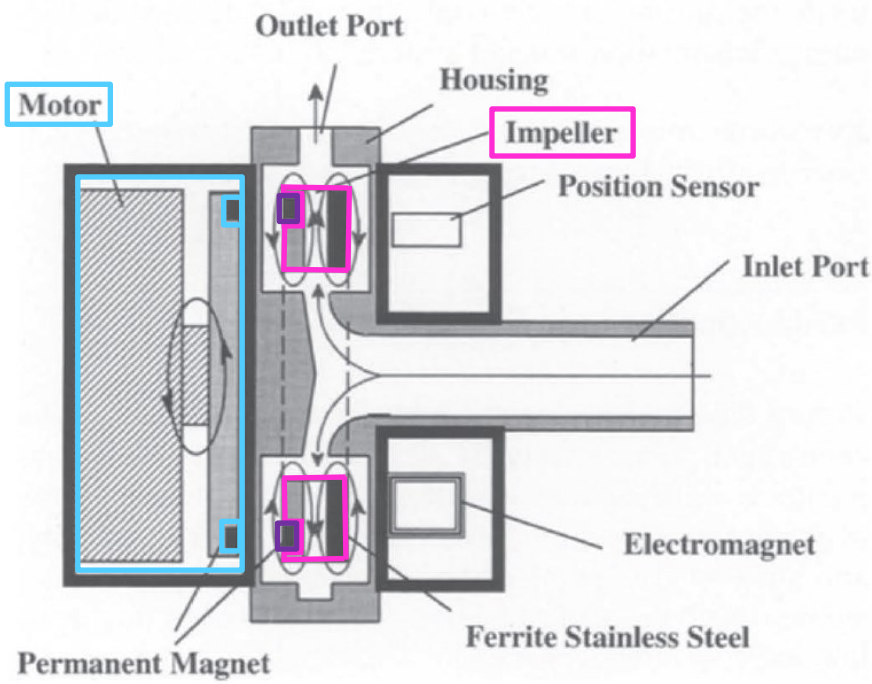


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

870. Accordingly, Akamatsu-1999 discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly*** ("impeller") *is*

positioned, and the magnetic drive system is positioned within a ***second chamber*** ("DC brushless motor") *sealed from the* ***first chamber*** ("permanent magnet")."

b. [23] The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.

871. Akamatsu-1999 discloses and/or renders obvious claim 23. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 22. I incorporate that discussion into my analysis for claim 23.

872. Akamatsu-1999 discloses that a "*wall of the chamber walls separates the* ***first chamber*** *from the* ***second chamber***." As discussed with respect to element [1E], Akamatsu-1999 discloses that the centrifugal pump includes a "housing" that is a "**surrounding rotor housing**" as recited in claim 1. *See supra* Section X.C.1.vi; Ex.1006 at 5, Fig. 2.

873. Akamatsu-1999 further discloses that "[t]he impeller rotates by a magnetic coupling between the impeller and the motor, and is suspended magnetically by the three electromagnets," and therefore does not require a rigid coupling to the second magnetic device for driving rotation. Ex.1006 at 4; *see also* Ex.1006 at 6 ("We have developed a sealless centrifugal pump with a magnetically suspended impeller (MSCP), which operates completely contact-free without any

material wear."), 3 ("Because the MSCP is a sealless rotor pump providing contact-free rotation of the impeller without any material wear, it is expected to be one of the most durable blood pumps.").

874. Therefore, as shown in Figure 2 the **surrounding rotor housing** (e.g., "a housing") of the centrifugal pump has a sealing wall between the **first magnetic device** (e.g., the "permanent magnet" within the impeller, Ex.1006 at 4, Fig. 2) and the **second magnetic device** (e.g., "DC brushless motor" having a "permanent magnet," Ex.1006 at 4, Fig. 2), reflected by the solid black line between the components:

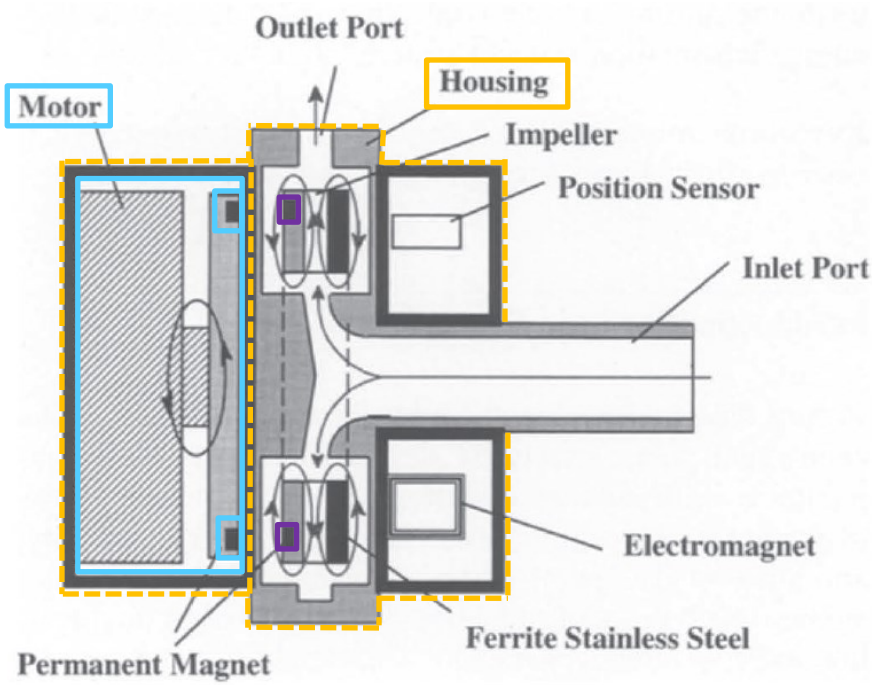


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 2 (annotated).

875. Accordingly, Akamatsu-1999 discloses that a "*wall of the chamber walls separates the **first chamber*** ("permanent magnet") *from the **second chamber*** ("DC brushless motor")."

10. Claim 24

a. [24] The system of claim 16, wherein the first magnetic device comprises a permanent magnet.

876. Akamatsu-1999 discloses claim 24. I have already explained how Akamatsu-1999 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 24.

877. Akamatsu-1999 discloses that "*the **first magnetic device** comprises a permanent magnet*."

878. This element is invalid for the same reasons discussed above in [1C] and [16C], thus, I incorporate that discussion into my analysis here.

879. Accordingly, Akamatsu-1999 discloses that "*the **first magnetic device** comprises a permanent magnet*."

11. Claim 26

a. [26] The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

880. Akamatsu-1999 discloses and/or renders obvious claim 26. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and

every element of claim 16. I incorporate that discussion into my analysis for claim 26.

881. Akamatsu-1999 discloses "*one or more sensors configured to deliver feedback signals to the **external control unit***."

882. As discussed with respect to elements [1L]-[1M], Akamatsu-1999 discloses a "controller" used to provide "electric current" to the "DC brushless motor" and the "electromagnets" located within the centrifugal pump. Ex.1006 at 3, 4. Akamatsu-1999 further discloses that "[t]he electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4. Akamatsu-1999 therefore discloses that the "three position sensors" provide feedback signals to the **external control unit** (e.g., the "controller, Ex.1006 at 3, 4) in order to control the electric current provided to the motor.

883. Accordingly, Akamatsu-1999 discloses "*one or more sensors* ("position sensors") *configured to deliver feedback signals to the **external control unit*** ("controller")."

12. Claim 28

884. Claim 26, depends from independent Claim 16. Accordingly, I address this dependent claim herein.

a. [28] The system of claim 16, wherein the heart assist pump device is a catheter device.

885. Akamatsu-1999 discloses and/or renders obvious claim 28. I have already explained how Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 28.

886. Akamatsu-1999 discloses that "*the **heart assist pump device** is a catheter device*."

887. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See*, e.g., Ex.1019, Complaint, Ex. 13. For the purposes of my analysis, I adopt that construction of "catheter device."

888. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], the centrifugal pump disclosed in Akamatsu-1999 includes a "catheter" which is an **inflow tube** (e.g., "inflow conduit" or "inlet port," Ex.1006 at 4) that is "inserted into the left ventricle through a cuff sutured to the left

ventricular apex." Ex.1006 at 4. Therefore, the centrifugal pump disclosed in Akamatsu-1999 is a catheter device.

889. Accordingly, Akamatsu-1999 discloses that "*the **heart assist pump device*** ("centrifugal pump") *is a catheter device*."

D. Ground 4: Schima in view of Akamatsu-1999 Renders Obvious Claims 1-5, 7, 10, 16-24, 26, and 28 of the 077 Patent

1. Claim 1

i. [1PRE] A system for assisting the blood circulation of a heart, comprising:

890. To the extent that the preamble is a limitation, Schima discloses "*a system for assisting the blood circulation of a **heart***."

891. For example, Schima discloses "a rotary pump for moving blood ["*assisting the blood circulation*"] and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing." Ex.1005, [0001]. For example, a POSITA would have understood that the publication classification codes published with Schima indicate that it is rotary blood pump for assisting a heart in a body. *See, e.g.*, Schima at "Publication Classification."

892. In addition, Schima discloses that its "rotary pump" is for *assisting…a heart* through its disclosure that the object of the invention is to overcome disadvantages with prior art heart assist pump devices. As discussed below in

connection with element [1A], Schima is silent regarding its placement in the body, but Schima describes "disadvantages" with a number of existing heart assist pump devices that were in development at the time, and then states that "[t]he present invention therefore has the object of overcoming the[] disadvantages" with those other heart assist pump devices. *See* Ex.1005, [0004] - [0009].

893. Accordingly, Schima discloses "*a system for assisting the blood circulation of a* ***heart***."

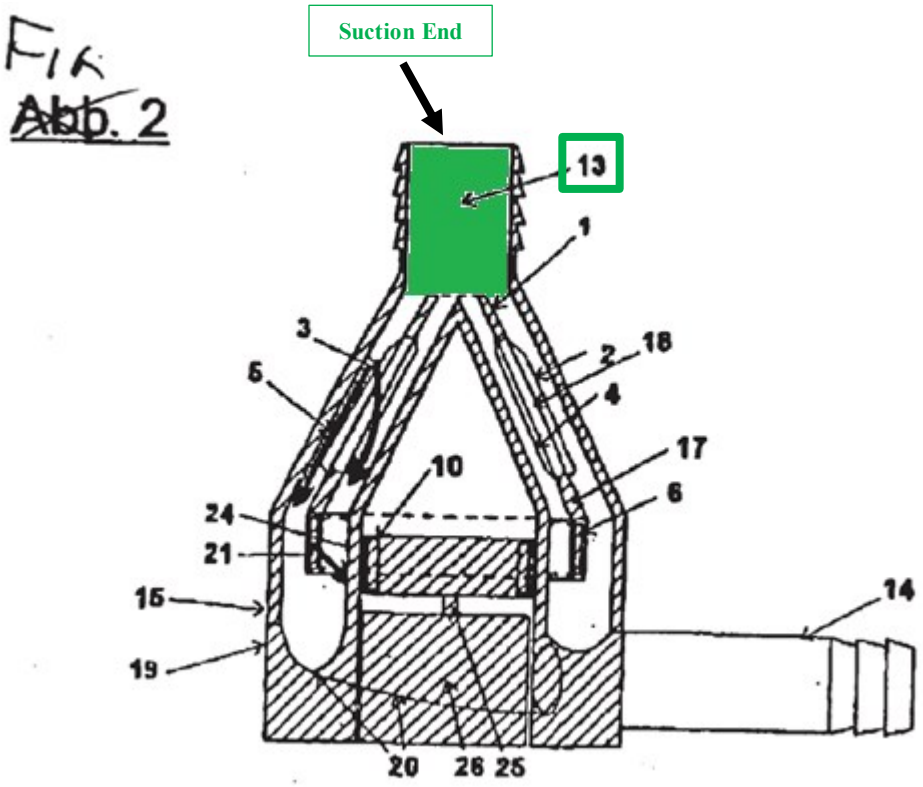
ii. [1A] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart

894. Schima discloses "***a heart assist pump device*** *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** *and having a suction end insertable into* ***a ventricle of the heart***."

895. The 077 Patent does not define the term "a heart assist pump device deliverable to the heart." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that assumes "a heart assist pump device deliverable to the heart" includes "an inflow cannula…inserted into a left ventricle of a patient's heart." *See* Ex.1019, (Complaint, Ex. 13). For the

purposes of my analysis, I adopt that construction of "d a heart assist pump device deliverable to the heart."

896. Schima discloses a "rotary pump for moving blood [*a heart assist pump device*]" Ex.1005, [0001], Abstract. Schima further discloses that "[t]he rotor 1 has at an inlet 13 ["*an inflow tube*"] an inlet opening 36 that distributes the incoming liquid to both sides of the rotor and against the point of the cone-shaped middle part 16." Ex.1005, [0012], *see also* Ex.1005, Claim 1. For example, Figure 2 (annotated) of Schima illustrates a cross section of the described "pump" (not labeled but refers to the entire structure shown in Figure 2) having an "inlet 13" (**green**):



Ex.1005, Fig. 2 (annotated).

897. A POSITA would have understood that the "pump" described in Schima is a "***heart assist pump device***" designed to be delivered to the heart such that the inlet tube 13 ["*an inflow tube*"] is *insertable into a ventricle of the heart*, because "the object of" "[t]he present invention" of Schima was directed at "overcoming…disadvantages" with previously known heart assist pump devices designed to be delivered to the heart. Ex.1005, [0009].

898. For example, Schima describes "overcoming" a number of existing heart assist pumps that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. Each of the heart assist pumps described in those publications were *deliverable to the heart and comprising: an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart.*

899. For example, Schima identifies a disadvantage with the centrifugal pump described in an "Akamatsu" publication. Ex.1005, [0004] (citing Akamatsu et al (*see e.g. Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638)). The same pump described in the Akamatsu article cited in article cited is described elsewhere, for example, in Akamatsu-1999, which I detail above in Ground 3. Ex.1006, [0004]. That pump described by Akamatsu is a "totally implantable left ventricular assist system (T-ILVAS)," which uses "a centrifugal pump with a magnetically suspended

impeller (MSCP)," which "operates completely contact-free without any material wear." Ex.1006 at 3, 7. The T-ILVAS described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle ["*an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart*"] through a cuff sutured to the left ventricular apex" during the *ex vivo* study performed on sheep. Ex.1006 at 4; *see also* Ex.1006 at Fig. 1 (illustration of *inflow tube…insertable into a ventricle of the heart*).

900. Similarly, Golding (U.S. Pat. No. 5,324,177, referenced in Schima, [0007]) describes "capable for use as heart or blood pumps, or ventricular assist devices ["*a heart assist pump device deliverable to the heart*"] that "can be sized for implantation within a living body, and is preferably employed as an assist device for humans. It is to be noted that the pump can be sized so as to even be implantable within a heart chamber ["*an inflow tube defining a blood inflow path and having a suction end insertable into a ventricle of the heart*"]. Ex.1027 (Golding), 1:9-11; 4:27-39.

901. Allaire (*Prototype Continuous Flow Ventricular Assist Device*, J. Artificial Organs 1996, Vol. 20, No. 7, pp.582-690 (Ex.1028), referenced in Schima, [0006], describes a prototype "Continuous Flow Ventricular Assist Device Number 2 (CFVAD2) system" that has "expected use…in an adult human." Ex.1028 at 583.

Allaire further describes that "the pump itself will be implanted in the abdominal cavity [*a heart assist pump device deliverable to the heart*]." Ex.1028 at 583. "The inlet to the CFVAD2 is a 14 mm internal diameter (ID) cannula that collects blood from the apex of the left ventricle ["*a heart assist pump device...comprising: an inflow tube...having a suction end insertable into a ventricle of the heart*"] and returns it through the outlet near the root of the aortic arch. Ex.1028 at 583.

902. Finally[21], Kung and Hart (*Design Considerations for Bearingless Rotary Pumps*, J. Artificial Organs 1997, Vol. 21, No. 7, pp. 645-650, Ex.1029), referenced in Schima [0005], describes another "rotary blood pump" used for "implantable cardiac support applications ["*a heart assist pump device deliverable to the heart*"]." Ex.1029 at 645.

903. Because Schima describes that "[t]he present invention therefore has the object of overcoming these" heart assist pump devices described above (Akamatsu, Golding, Allaire, Kung and Hart), Schima is describing that its "present

[21] Schima also identifies another heart assist pump device as described in "Woodward et al (WO 00/12587)." Schima [0008]. However, I could not find an application with that publication number listing Woodward. I note, however, that a Jonathan Woodard is listed as an inventor to several patents assigned to Thoratec which also relate to heart assist pump devices delivered to a heart, which would be consistent with the others. *See, e.g.*, US 2005/0196293.

invention" is also a "*heart assist pump device*," designed to be *delivered to a heart* such that the "inlet tube 13 ['*an inflow tube...having a suction end*']" "*insertable into a ventricle of the heart*."

904. Accordingly, Schima discloses "***a heart assist pump device*** ("pump," Ex.1005) *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** ("inlet 13," Ex.1005) *and having a suction end insertable into* ***a ventricle of the heart***."

905. To the extent one asserts that Schima's "rotary pump for moving blood" is not delivered to the heart so that the suction end of the inlet 13 is inserted into a ventricle of a heart, it would have been obvious to a POSITA as of February 27, 2007 that Schima's pump was designed for such delivery. As discussed above, Schima describes a number of existing heart assist pumps that were in development at the time. *See* Ex.1005, [0004], [0005], [0006], [0007], [0008]. For example, the "totally implantable left ventricular assist system (T-ILVAS)" described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured to the left ventricular apex ['*having a suction end insertable into a ventricle of the heart*']" during the *ex vivo* study performed on sheep. Ex.1006 at 4.

906. As I detail below in Section X.D.13 and incorporated by reference here, a POSITA would have been motivated to deliver the "pump" described in Schima to a heart as described in Akamatsu-1999 because the disclosures are directed to the same problems faced in existing blood pumps at the time—the improvement of rotary blood pumps used to assist the circulation of blood in the heart. Therefore, a POSITA would have had a reasonable expectation of successfully addressing those problems in doing so. Delivering the "pump" to a heart would have required merely using a known component (an inlet tube) in a known way by inserting the inlet tube 13 into the left ventricle of the heart, as described in Akamatsu-1999. For example, Figure 1 (annotated) illustrates the Akamatsu-1999 T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inflow conduit (**green**) of the T-ILVAS is "*insertable into a ventricle of the heart*:"

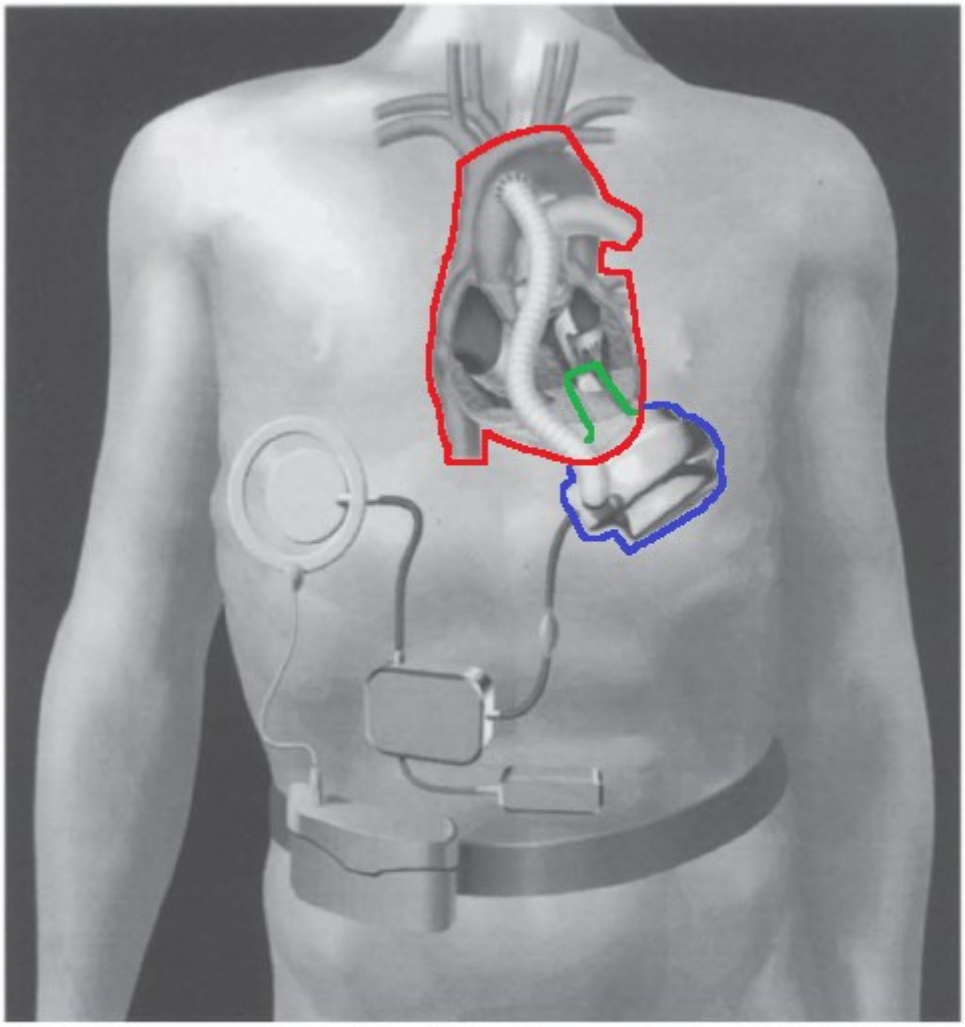


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated).

907. Therefore, it is my opinion that the resultant combination of Schima and Akamatsu-1999 would have been predictable, and a POSITA would have been motivated and had a reasonable expectation of success because the delivery of an LVAS was well known and developed in the field for the reasons stated below in

Section X.D.13. Thus, implementing the combination would have been well within the ordinary skillset of a POSITA at the time.

908. Accordingly, Schima in view of Akamatsu-1999 renders obvious "***a heart assist pump device*** ("pump," Ex.1005) *deliverable to the* ***heart*** *and comprising: an* ***inflow tube defining a blood inflow path*** ("inlet 13," Ex.1005) *and having a suction end insertable into* ***a ventricle of the heart*** ("inserted into the left ventricle," Ex.1006).

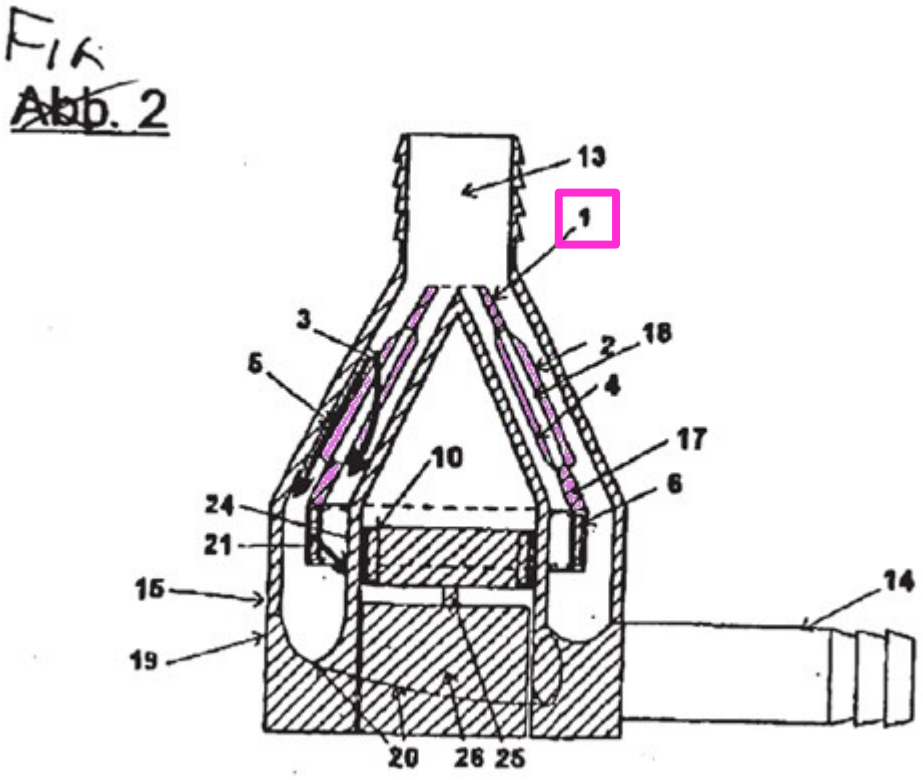
iii. [1B] a magnetically driven rotor assembly configured to be axially aligned with the inflow tube and to be spaced apart from the suction end when the suction end of the inflow tube is inserted into the ventricle

909. Schima discloses that "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow tube*** *and to be spaced apart from the suction end when the* ***suction end of the inflow tube*** *is inserted into the* ***ventricle***."

910. For example, the "pump" described in Schima includes a "rotor 1 [***rotor***]" that "holds rotor magnets 6 that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. Further, Schima discloses that "the drive can…be an electric motor 26 which drives a rotating disk 24 with magnets 10 ['***magnetically driven***']." Ex.1005, [0013].

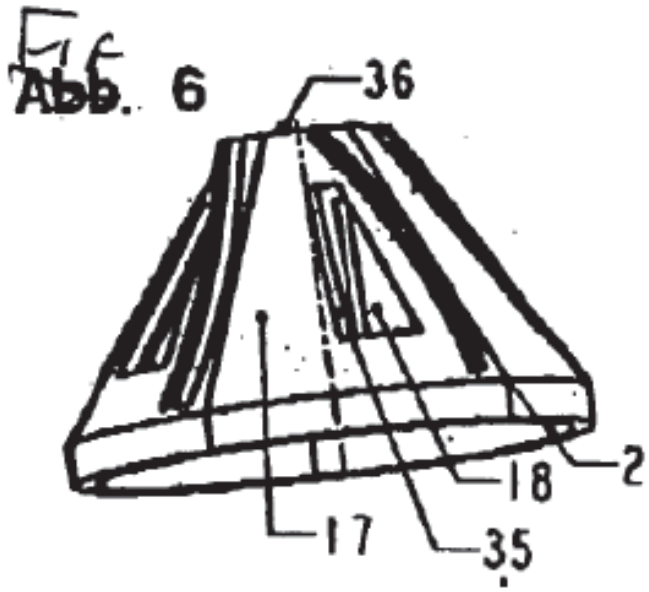
Thus, the "rotor 1" described in Schima is a "***magnetically driven rotor***" and "magnets 6" is a **first magnetic device**. Together, **rotor 1** and **magnets 6** are the **magnetically driven rotor assembly** as recited in claim 1. As discussed below with respect to element [1C], the **magnets 6** are embedded within **rotor 1** such that the **magnets 6** are also axially aligned with the **inflow tube** as discussed here.

911. Figure 2 (annotated) of Schima illustrates the rotor 1 (**pink**) of the pump:



Ex.1005, Fig. 2 (annotated).

912. Figure 6 of Schima shows an oblique view of the "rotor 1" separated from the pump for clarity:

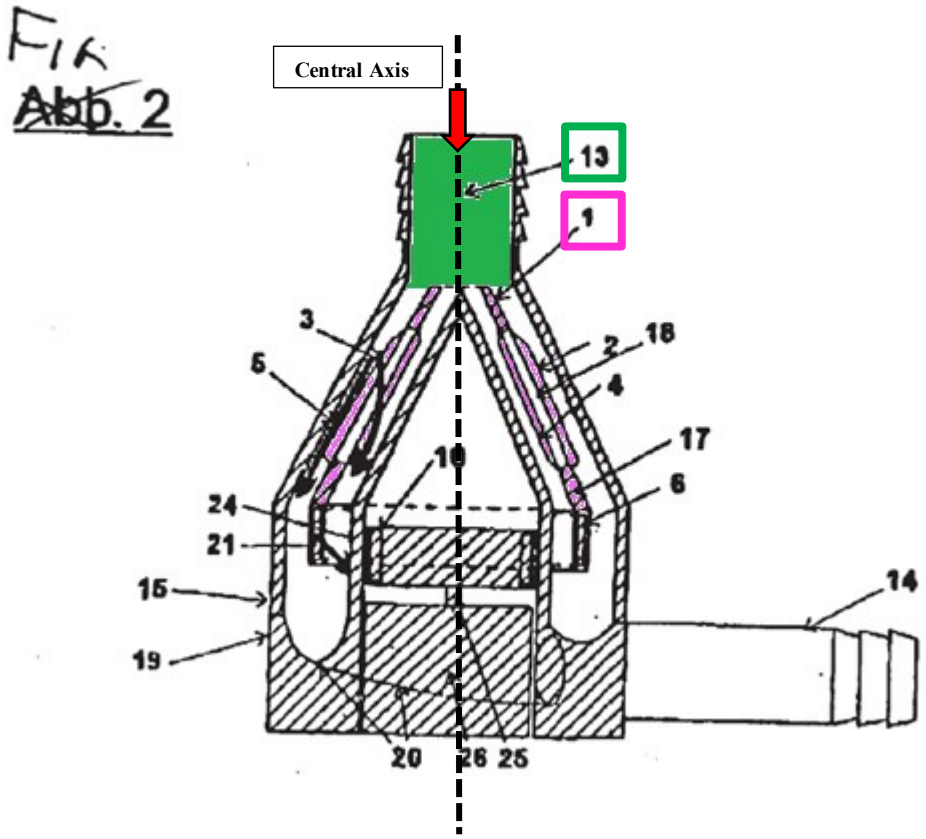


Ex.1005, Fig. 6.

913. For components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis") in space. The blood pump described in Schima has a central axis that is configured in axial alignment with the **inflow tube** (e.g., "inlet tube 13," Ex.1005, [0012]) so as to provide the flow of blood to the **magnetically driven rotor assembly** (e.g., "rotor 1," and "magnets 6" Ex.1005, [0012]). Specifically, Schima states that the "flow [from *the inflow tube*]" is "preferably axially against ['*axially aligned with the*

magnetically driven rotor"] the conical upper surface of the middle part 16" of the pump housing 30." Ex.1005, [0012].

914. For example, Figure 2 (annotated) of Schima illustrates the alignment of the rotor 1 (**pink**) and the inlet 13 (**green**) of the pump along a central axis and the flow path of blood from the left ventricle the heart (**red** arrow):



Ex.1005, Fig. 2 (annotated).

915. Indeed, the pump described in Schima is a *centrifugal* pump (producing "centrifugal flow components," Ex.1005, [0012]) and by design, fluid enters a centrifugal pump along its axis towards the rotor and is accelerated by centrifugal

force toward the circumference of the impeller, collected by a volute (the "spiral shaped outlet passage 20," Ex.1005, [0012]) and then discharged through an outlet 14. Thus, by definition of it being a centrifugal pump, "*the magnetically driven rotor is axially aligned with the inflow tube*."

916. Accordingly, Schima discloses that "*a **magnetically driven rotor assembly*** ("rotor 1" and "magnets 6," Ex.1005) *configured to be axially aligned with the **inflow tube*** ("inlet 13," Ex.1005) *and to be spaced apart from the suction end when the **suction end of the inflow tube** is inserted into the **ventricle***."

iv. [1C] the magnetically driven rotor assembly comprising a first magnetic device that is rigidly coupled to and axially adjacent to a rotor

917. Schima discloses "*the **magnetically driven rotor assembly** comprising a **first magnetic device** that is rigidly coupled to and axially adjacent to a **rotor***."

918. As discussed above with respect to element [1B], the magnetically driven rotor assembly **rotor 17** comprises **magnetic pieces 88** which are rigidly coupled and axially adjacent **impeller 74**.

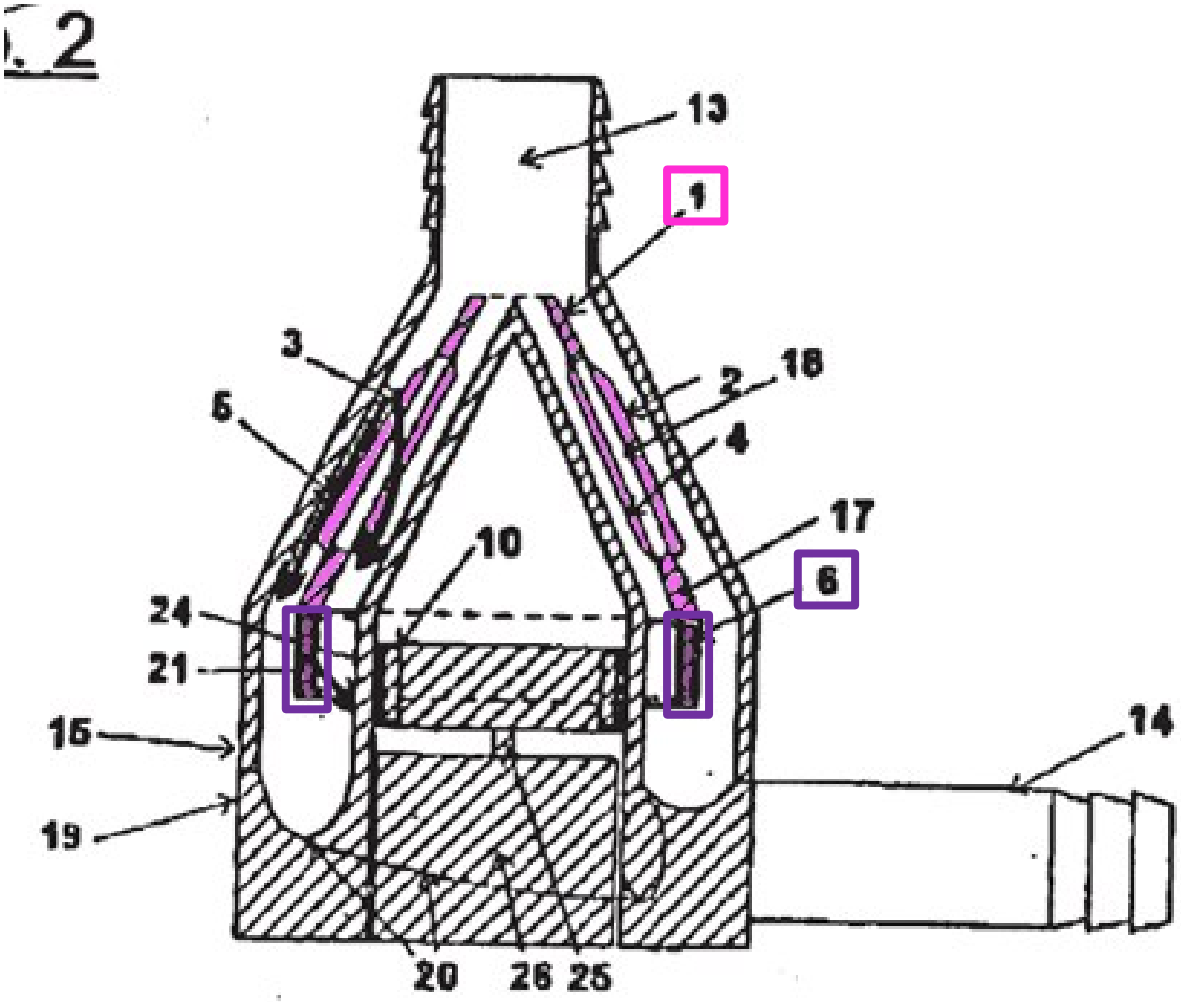
919. For example, "[t]he rotor holds ['*coupled to*'] **rotor magnets 6** that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. As discussed with respect to element [1B], the "rotor 1" is a **magnetically driven rotor assembly**. *See supra* Section

X.D.1.iii. The "rotor magnets 6" which transfer rotation energy to the rotor 1 are a **first magnetic device** which is rigidly coupled to the **magnetically driven rotor** because the rotor magnets 6 are held by the rotor 1.

920. As will be discussed with respect to elements [1G] and [1J], the "drive" for the "*magnetically driven*" rotor can be an "electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25," thereby creating a "magnetic force 21" with the "rotor magnets 6." Ex.1005, [0012], [0013]; *see infra* Sections X.D.1.viii, X.D.1.xi, and X.D.1.xii.

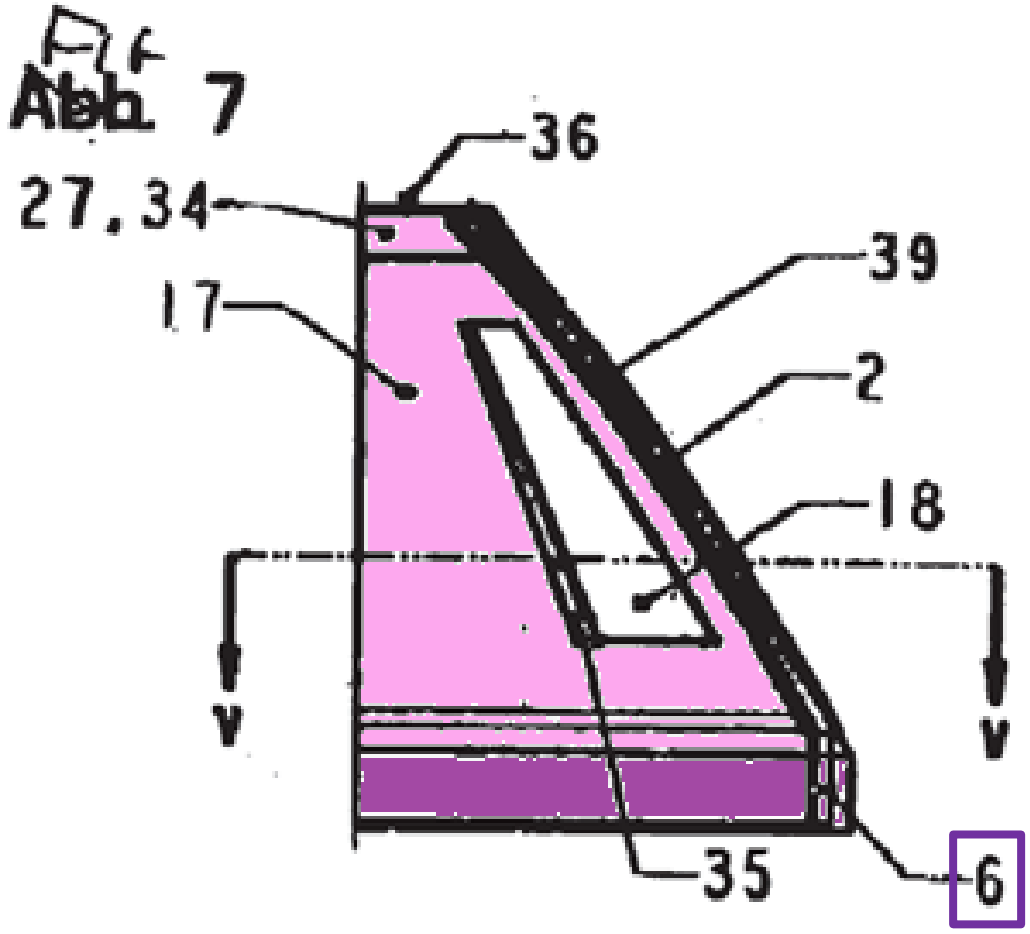
921. In order for the "magnetic force 21" to drive the rotation of the of the rotor 1 via the rotor magnets 6, the rotor magnets 6 are *axially adjacent* to the rotor 1, such that, when the magnetic force is applied, the rotor 1 may rotate about its axis. Ex.1005, [0012], [0013].

922. Figure 2 (annotated) of Schima illustrates that the rotor magnets 6 (**purple**) are rigidly coupled and axially adjacent to the rotor 1 (**pink**):



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

923. Figure 7 (annotated) of Schima shows a side view of the rotor 1 (**pink**) removed from the pump for clarity, which holds rotor magnets 6 (**purple**), which "can be formed by a continuous magnetic ring":



Ex.1005, Fig. 7 (annotated).

924. Accordingly, Schima discloses "*the* ***magnetically driven rotor assembly*** ("rotor 1," Ex.1005) *comprising a* ***first magnetic device*** ("rotor magnets 6," Ex.1005) *that is rigidly coupled to and axially adjacent to a* ***rotor***."

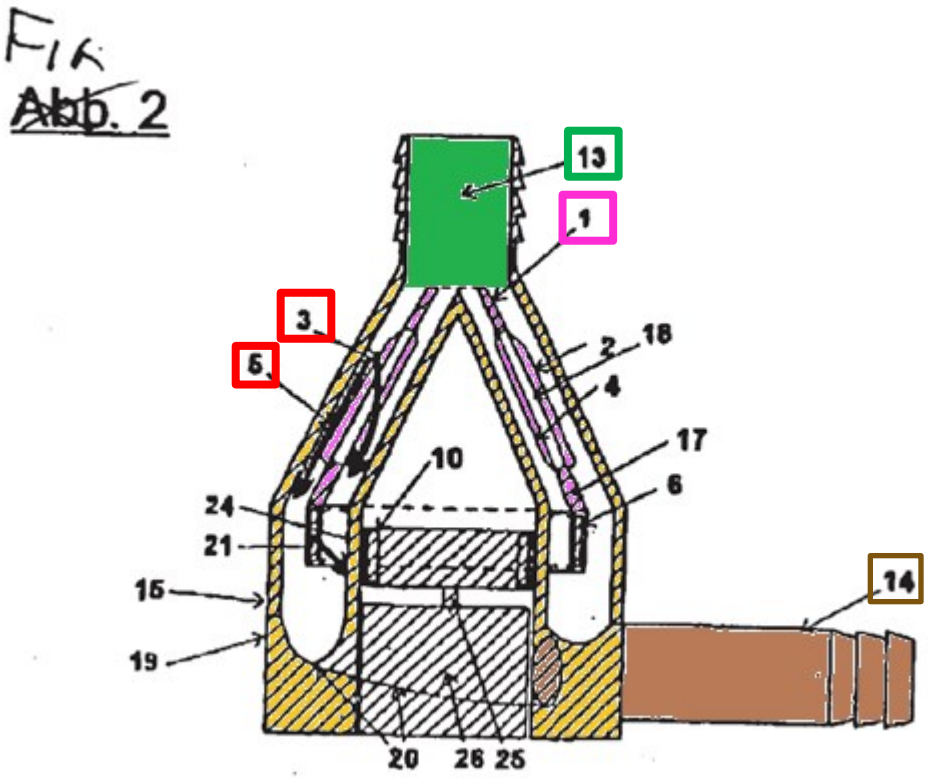
v. [1D] [the rotor] having guide surfaces to produce centrifugal flow components

925. Schima discloses that **rotor** "*having guide surfaces to produce centrifugal flow components*."

926. Schima discloses that "[t]he rotor 1 has as **flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5** directed against the housing." Ex.1005, [0012]; *see also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for **contact-free journaling and stabilizing of the rotor in the housing**."), Claim 1 ("… the flow components (**5**) directed against the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

927. A POSITA would understand the "flow surfaces 2 and 4 vanes" are "*guide surfaces*" as recited in Claim 1D, that "*produce centrifugal flow components* 3 and flow components 5 directed against the housing." Ex.1005, [0012].

928. Figure 2 (annotated) illustrates the *centrifugal flow components* 3 and 5 (**red**, included in the original Figure 2) of the blood flowing from the inlet 13 (**green**) to the outlet 14 (**brown**), which are produced in response to the rotation of the magnetically driven rotor (**pink**), and directed against the housing 30 (**orange**) so as to create a "contact free journaling and stabilizing of the rotor in the housing":



Ex.1005, Fig. 2 (annotated).

929. Accordingly, Schima discloses the **rotor** ("rotor 1," Ex.1005) "*having guide surfaces to produce centrifugal flow components* ("*centrifugal flow components* 3," Ex.1005)."

vi. [1E] the magnetically driven rotor assembly being rotatable about a central axis within a surrounding stationary housing to act upon blood flowing from the inflow tube to the rotor

930. Schima discloses that "*the **magnetically driven rotor assembly** being rotatable about a **central axis** within **a surrounding stationary housing** to act upon blood flowing from the **inflow tube** to the **rotor**.*"

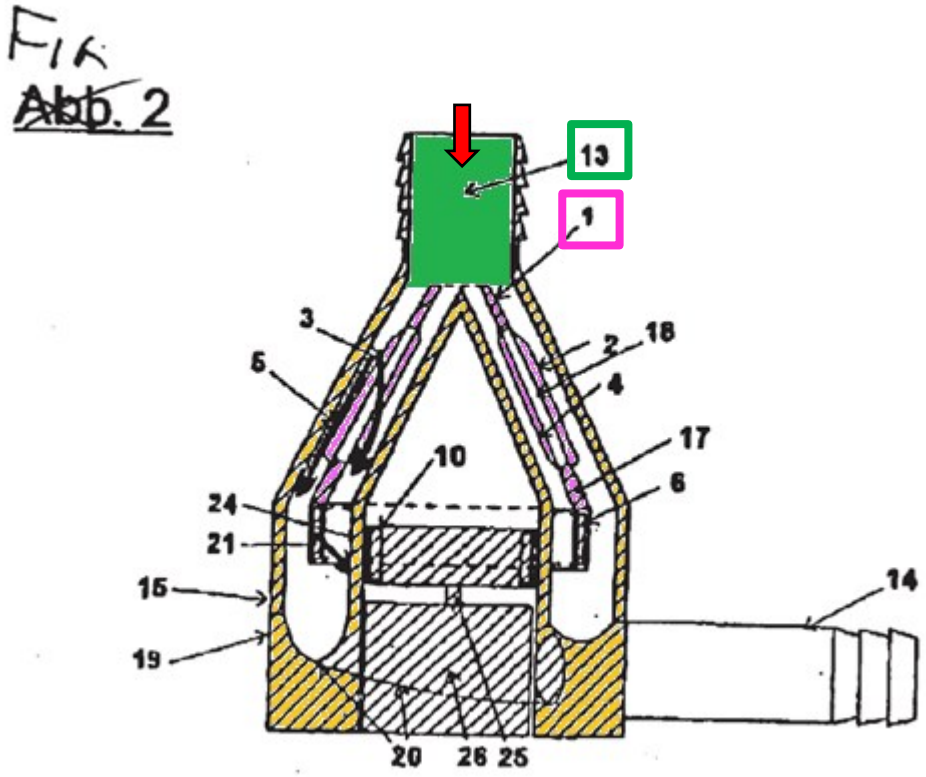
931. As discussed above with respect to element [1B], the magnetically driven rotor assembly comprises **rotor magnets 6** which are rigidly coupled and axially adjacent **rotor 1**.

932. For example, Schima describes that the "rotor 1…produce[s] centrifugal flow components 3 and flow components 5." This is achieved by "hollow conical rotor 1 rotat[ing] in a pump housing 30 ['***a surrounding stationary housing***'] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, centering of the hollow conical rotor in the middle part 16 ['*rotatable within*'] of the housing lower part 19 being effected by the flow

components 5 directed against the housing, this flow ['*to act upon blood flowing from the inflow tube to the rotor*'] being preferably axially against the conical upper surface of the middle part 16." Ex.1005, [0012].

933. Thus, the **magnetically driven rotor assembly** (e.g., "rotor 1") is rotatable within a **surrounding stationary housing** (e.g., "pump housing 30") of the centrifugal pump to act upon blood flowing from the ***inflow tube*** (e.g., "inlet 13") toward the rotor.

934. Figure 2 (annotated) of Schima illustrates that the rotor 1 (**pink**) *rotates within* the pump housing 30 (**orange**, labeled in Figure 1), such that it rotates between the "hollow conical upper part 15 and "the middle part 16" of the housing (labeled in Figure 1), to act upon blood flowing (**red** arrow) from the inlet 13 (**green**) toward the rotor:



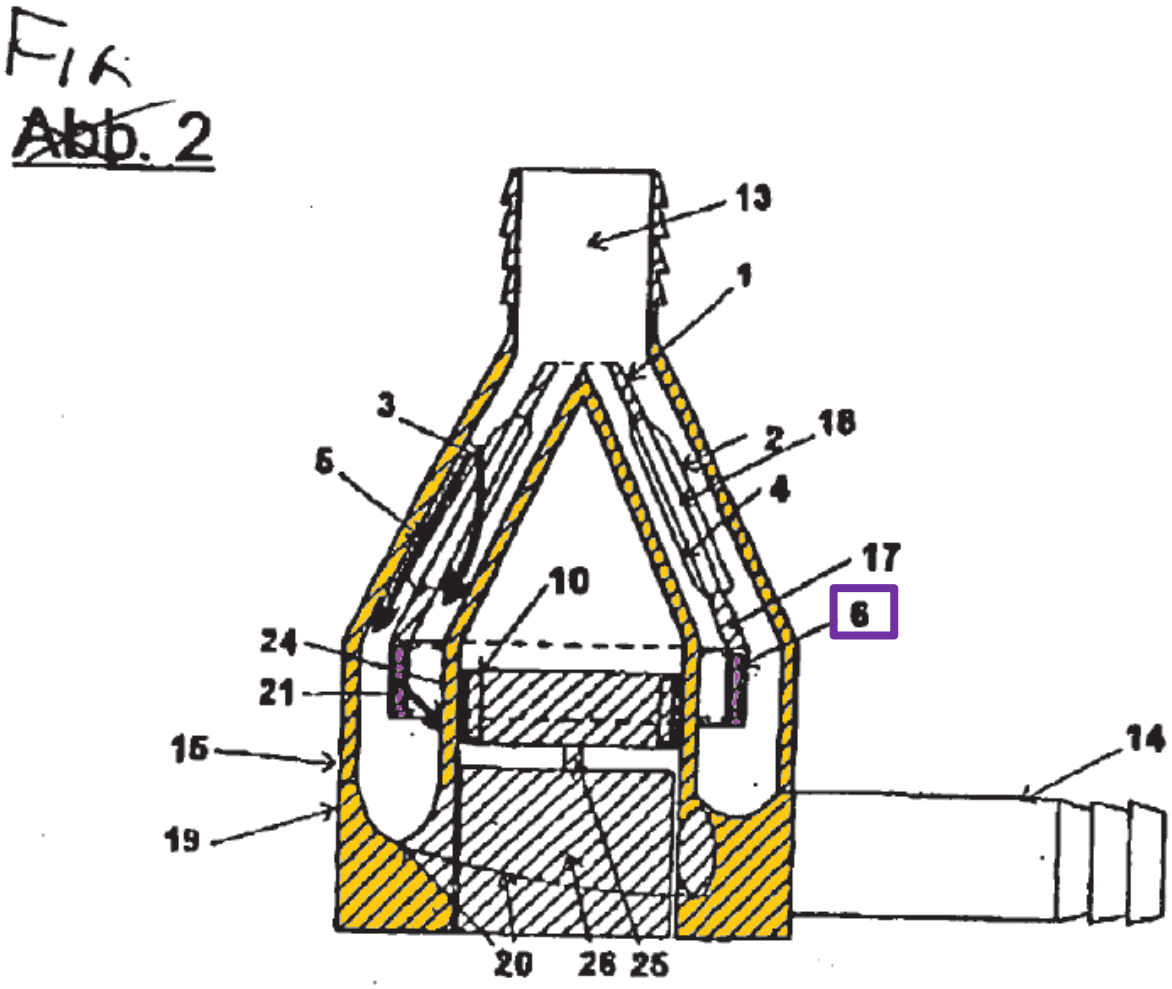
Ex.1005, Fig. 2 (annotated).

935. For example, Schima describes that the "hollow conical rotor 1 rotates in a pump housing 30 ['*the surrounding rotor housing*'] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, centering of the hollow conical rotor in the middle part 16 of the housing lower part 19 being effected by the flow components 5 directed against the housing, this flow being preferably axially against the conical upper surface of the middle part 16." Ex.1005, [0012].

936. The "rotor 1" is a **magnetically driven rotor**. *See supra* Section X.D.1.iii. And as discussed with respect to element [1C], the "rotor magnets 6" held by the rotor 1 are a **first magnetic device**. Ex.1005, [0012].

937. Thus, the "pump housing 30" of the pump is a ***surrounding rotor housing*** which houses a **first magnetic device** (e.g., "rotor magnets 6" held by the rotor 1," Ex.1005, [0012]).

938. Figure 2 (annotated) of Schima illustrates cross-sectional view of the pump having rotor 1, which holds rotor magnets 6 (**purple**) within the pump housing 30 (**orange**):



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

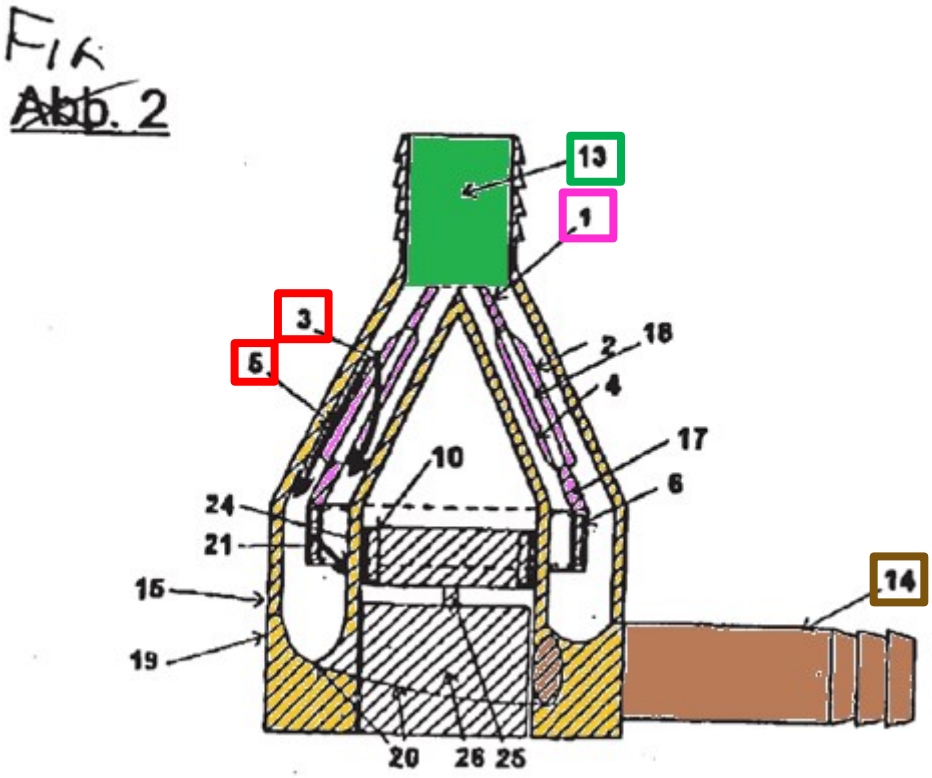
939. Accordingly, Schima discloses that "*the **magnetically driven rotor assembly*** ("rotor 1" and "rotor magnets 6") *being rotatable about a central axis within **a surrounding stationary housing*** ("pump housing 30," Ex.1005) *to act upon blood flowing from the **inflow tube*** ("inlet 13," Ex.1005) *to the **rotor*** ("rotor 1," Ex.1005)."

vii. [1F] while the magnetically driven rotor assembly is entirely spaced apart from the stationary housing by a gap sized for passage of the blood;

940. Schima in view of Akamatsu-1999 discloses that "*the **magnetically driven rotor assembly** is entirely spaced apart from the **stationary housing** by a gap sized for passage of the blood*."

941. As discussed with respect to element [1G] below, Schima discloses "contact-free journaling and stabilizing of the rotor in the housing," which discloses this limitation. Ex.1005, [0010]. In particular, Schima discloses that "[t]his hollow conical **rotor 1 rotates** in a pump housing 30 ['*magneto coupling* (discussed in more detail in [1G]) *orients the magnetically driven rotor'*] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part 15, **centering of the hollow conical rotor in the middle part 16** ['*the magnetically driven rotor remains adjacent to and spaced apart from the surrounding rotor housing*'] of the housing lower part 19 being **effected by the flow components** 5 directed against the housing, this flow being preferably axially against the conical upper surface of the middle part 16. This centering can however also be wholly or additionally effected by flow components (5) directed against the housing or centrifugally (3) against the hollow conical upper part 15." Ex.1005, [0012].

942. Figure 2 (annotated) illustrates the centrifugal flow components 3 and 5 (**red**, included in the original Figure 2) of the blood flowing from the inlet 13 (**green**) to the outlet 14 (**brown**), which are produced during by the rotation of the rotor 1 (**pink**), and directed against the housing 30 (**orange**) so as to create a "contact free journaling and stabilizing of the rotor in the housing":



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that when the **magnetically driven rotor** is rotated ("**rotor 1 rotates**"), the **magnetically driven rotor** remains adjacent to and spaced apart from the surrounding stationary housing ("**housing 30**") by the blood flowing (**the "centrifugal flow**

components" 3 and 5) from the inflow tube ("**inlet 13**") and to the blood outflow port ("**outlet 14**") so as to create a "contact free journaling and stabilizing" when the rotor 1 is in rotation. Ex.1008, [0010], [0012].

943. Accordingly, Schima discloses that "*the **magnetically driven rotor assembly*** ("rotor 1" and "rotor magnets 6") *is entirely spaced apart from the **stationary housing*** ("pump housing 30," Ex.1005) *by a gap* ("contact-free journaling" Ex.1005) *sized for passage of the blood*."

viii. [1G] a second magnetic device axially aligned with the inflow tube and positioned to magnetically drive rotation of the magnetically driven rotor assembly via a magneto coupling with the first magnetic device

944. Schima discloses that "*a **second magnetic device** axially aligned with the **inflow tube** and positioned to magnetically drive rotation of the **magnetically driven rotor assembly** via a magneto coupling with the **first magnetic device***."

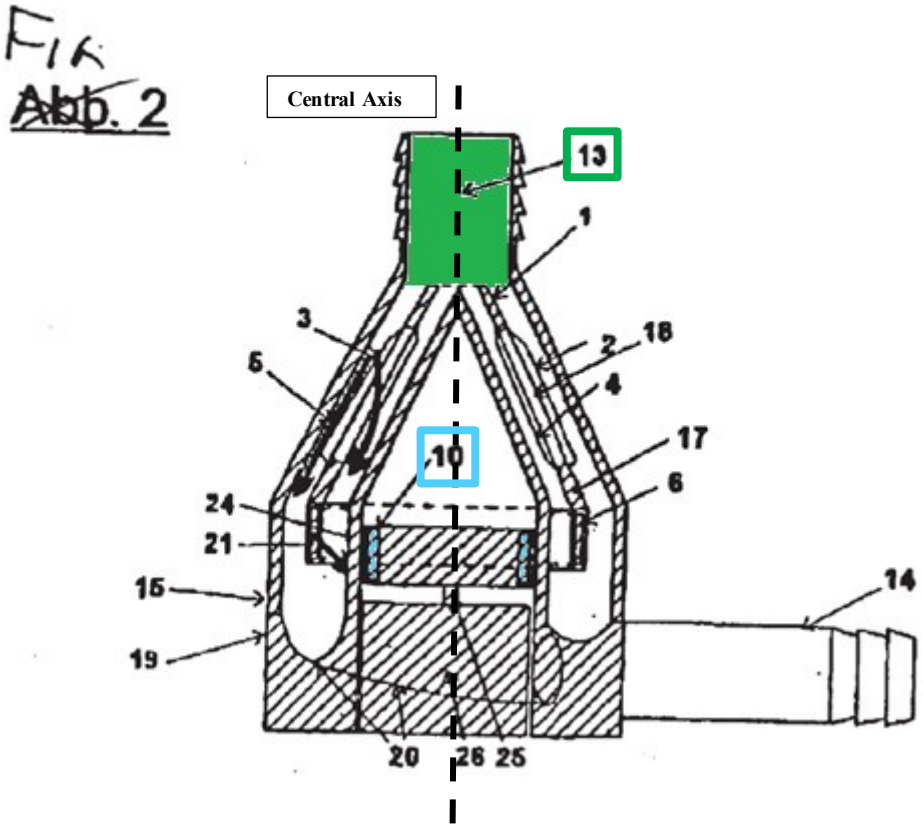
945. As discussed above with respect to element [1B], the magnetically driven rotor assemblycomprises **rotor magnets 6** which are rigidly coupled and axially adjacent **rotor 1**.

946. As discussed above with respect to element [1B], for components to be "axially aligned" as recited in Claim 1, the components are configured such that they are colinear, or in the same line (or "axis" of rotation) in space. *See supra* Section

X.D.1.iii. The **heart assist pump device** (e.g., "pump," Ex.1005, [0012]) described in Schima has an **inflow tube** (e.g., "inlet 13," Ex.1005, [0012]) through which blood flows to the **magnetically driven rotor** (e.g., "rotor 1," Ex.1005, [0012]), which is driven by the magnetic coupling between the **first magnetic device** (e.g., the "rotor magnets 6," Ex.1005, [0012]) and the **second magnetic device** (e.g., "magnets 10" within "rotating disk 24", Ex.1005, [0013]).

947. Each of the rotor 1, rotor magnets 6, and the magnets 10 within the rotating disk 24 driven by the electric motor 26 are "*axially aligned*" with the inlet 13. Ex.1005, Fig. 2. Indeed, the pump described in Schima is a *centrifugal* pump (producing "centrifugal flow components," Ex.1005, [0012]) and by design, fluid enters a centrifugal pump along its axis towards the rotor and is accelerated by centrifugal force toward the circumference of the impeller, collected by a volute and then discharged through an outlet. Said another way, an "*axially aligned…inflow tube*" is a characteristic feature of a centrifugal pump.

948. Figure 2 (annotated) illustrates a cross-sectional view of the pump where the "magnets 10" (**light blue**) within rotating disk 24 are axially aligned with the inlet 13 (**green**) along the central axis (**black**):



Ex.1005, Fig. 2 (annotated).

949. Further, as discussed in Section VII.A.1, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "magneto coupling" to mean "a transfer of torque from one rotating magnetic component to another rotating magnetic component via a magnetic field." *See supra* Section VII.A.1. For the purposes of my analysis in this Ground, I assume that the plain and ordinary meaning is correct, and Patent Owner's apparent broader construction (in parallel litigation) of "magneto coupling" to also include not only a transfer of torque from one rotating magnetic component to another rotating magnetic component, but also

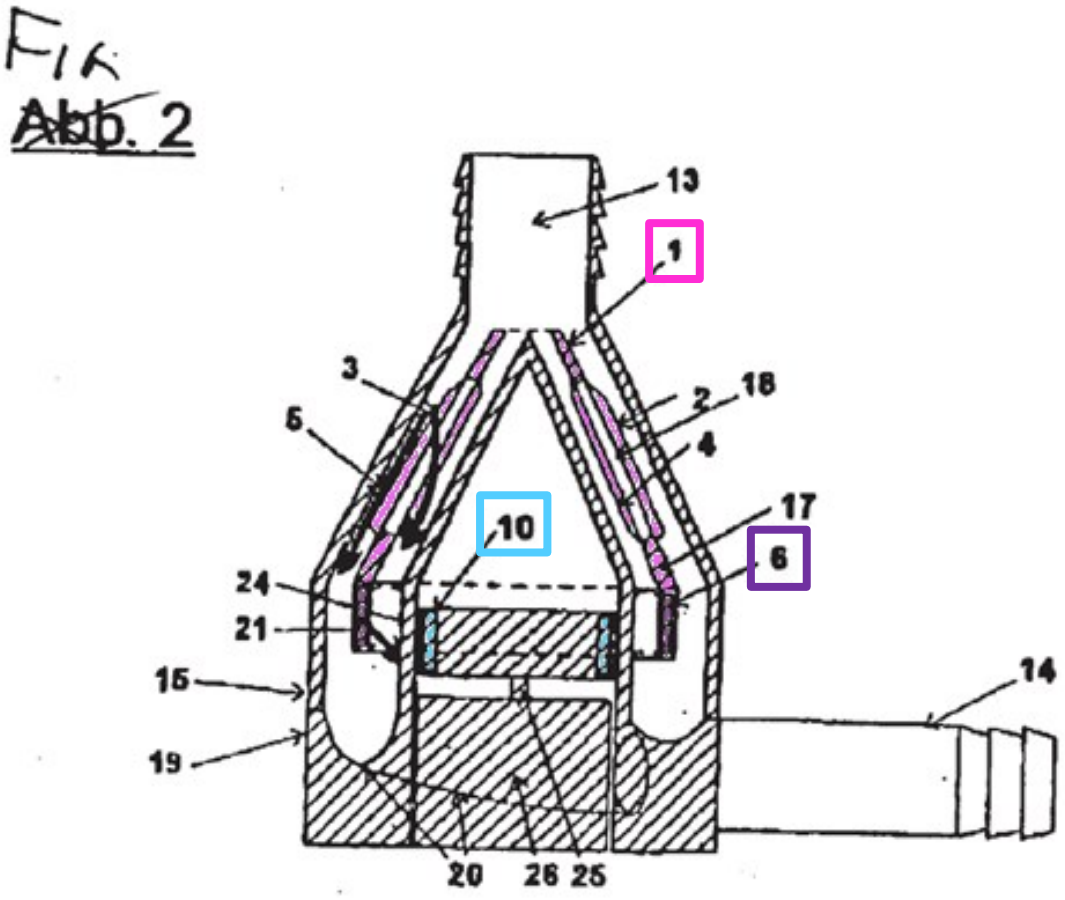
to include "a transfer of torque from one *stationary* magnetic component (i.e., a stator) to another rotating magnetic component using an *electro*magnetic field," is incorrect. *See* Ex.1019.

950. Schima, however, discloses "magneto coupling" under both constructions, thus the claims are invalid under any interpretation.

951. Based on my understanding of the plain and ordinary meaning of the term "magneto coupling," Schima describes a *magneto coupling* between the **second magnetic device** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) and the **first magnetic device** (e.g., the "rotor magnets 6" held by the rotor 1, Ex.1005, [0012]). For example, Schima discloses that the "rotor holds rotor magnets 6 that preferably **transfer rotation energy** and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. "As shown in FIG. 2, the drive can also be an electric motor 26 which drives a rotating disk 24 with magnets 10 by means of a shaft 25. This embodiment has the advantage that no electrical energy is used to journal the rotor and as a result the axial offset of the disk 24 ensures an axial component for the **magnetic force 21**." Ex.1005, [0013]; *see also* Ex.1005, Claim 9 (The pump according to one of the preceding claims, characterized in that in the region of the lower edge (41) the rotor (1) is provided with **a plurality of rotor**

magnets (6) or a magnetic ring **that cooperates with magnets (10, 12)** in the housing (30) and/or with a magnetic drive.").

952. Figure 2 (annotated) illustrates that the "magnets 10" (**light blue**) with rotating disk 24 are positioned to magnetically drive rotation of the rotor 1 (**pink**) via a *magneto coupling* ("transfer rotation energy" using the "magnetic force 21") with the rotor magnets 6 (**purple**):



Ex.1002, Fig. 2 (annotated).

953. Note that Figure 2 is a cross-sectional view of the pump and the rotor holding rotor magnets 6 is understood to surround the central axis, essentially mirroring the rotation of the magnets 10 within rotating disk 24, which is rotated by electric motor 26.

954. Schima also discloses "*magneto coupling*" under the Patent Owner's apparent construction. To the extent that the term "*magneto coupling*" is interpreted broadly according to Patent Owner's apparent construction, Schima also discloses an embodiment of the rotor 1 where the "rotor magnets work as shown in FIG. 1 with a stator 12 inside the housing lower part 19 having coils 9 creating a rotating magnetic field. An axial offset of the rotor magnets 6 and stator 8 causes the coupling force 21 to be effective at an angle and provide an axial component for additional stabilizing of the rotor 1." Ex.1005, [0012].

955. Thus, under either interpretation of the term, Schima discloses that a ***second magnetic device*** (either "magnets 10" in the first embodiment, or "stator 12" in the second embodiment), is positioned to magnetically drive rotation of the rotor 1 via a magneto coupling with the rotor magnets 6.

956. Accordingly, Schima discloses that "*a* ***second magnetic device*** ("magnets 10," Ex.1005) *axially aligned with the* ***inflow tube*** *and positioned to magnetically drive rotation of the* ***magnetically driven rotor assembly*** ("rotor 1" and

"rotor magnets 6," Ex.1005) *via a magneto coupling with the* ***first magnetic device*** ("rotor magnets 6," Ex.1005)."

ix. [1H] while [the second magnetic device is] being spaced apart and sealed from both the rotor and the first magnetic device of the magnetically driven rotor assembly

957. Schima discloses that the ***second magnetic device*** is positioned according to element [1H] "*while being spaced apart and sealed from both the* ***rotor*** *and the* ***first magnetic device*** *of the* ***magnetically driven rotor assembly.***"

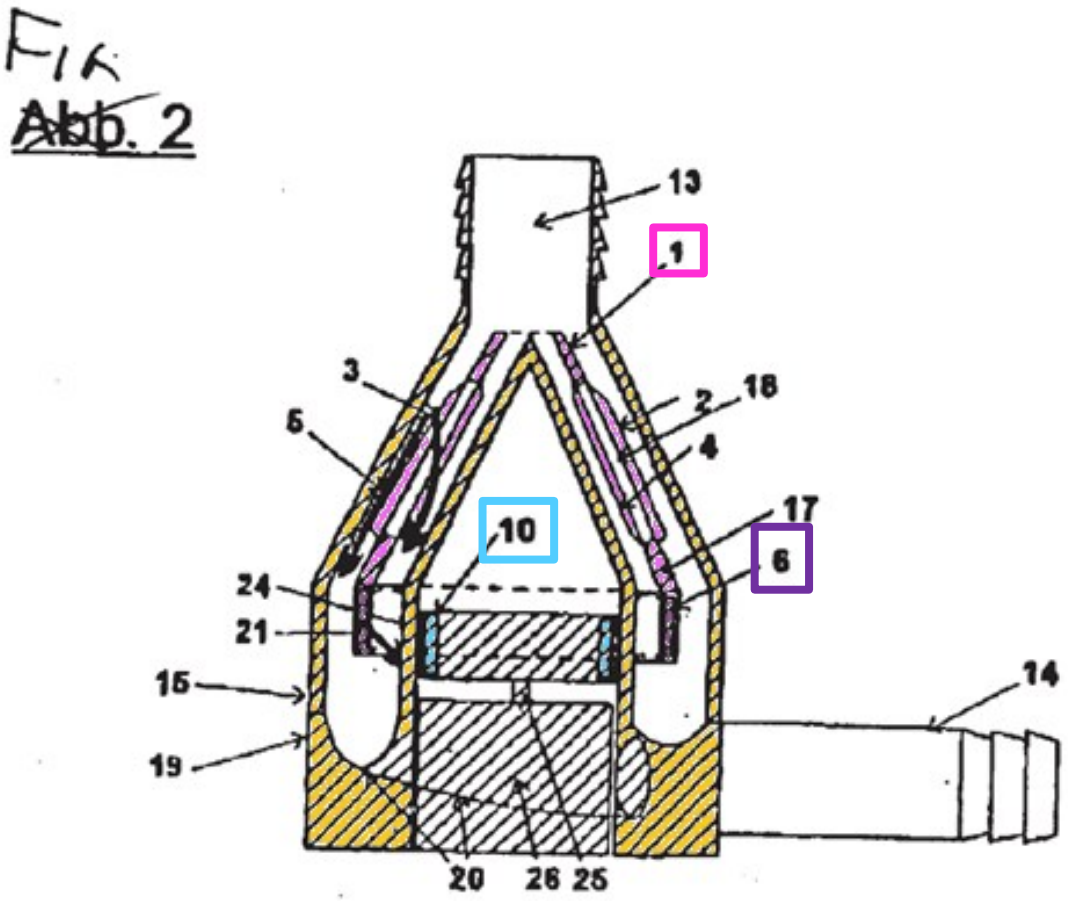
958. Schima describes that its invention relates to a rotary pump, that has a rotor 1 that is able to rotate "contact-free" ["*being spaced apart*"] from the housing. Ex.1005, [0010], Abstract, Claim 1. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow and dead-water areas" could create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

959. According to Schima, "therefore solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. The

invention in Schima "is characterized in that the rotor has flow-control surfaces for producing centrifugal flow components and flow components directed against the housing, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for contact-free ['*being spaced apart*'] journaling and stabilizing of the rotor in the housing." Ex.1005, [0010].

960. As discussed for element [1G], this contact-free spacing is accomplished in Schima by the use of the "magnets 10" within "rotating disk 24" driven by electric motor 26, which drive rotation of rotor magnets 6 by the "magnetic force 21," without the need for contact between the magnetic devices. *See supra* Section X.D.1.viii.

961. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump having magnets 10 (**light blue**) that are spaced apart and sealed from the rotor (**pink**) holding rotor magnets 6 (**purple**) by the housing 30 (**orange**):



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) *spaced apart and sealed from both the* ***magnetically driven rotor*** (e.g., "rotor 1" Ex.1005, [0012]) *and the* ***first magnetic device*** (e.g., "rotor magnets 6", Ex.1005, [0012]). Schima also discloses "[a] spiral-shaped outlet passage 20 in the lower housing part 19" which "leads to an outlet 14," suggesting that the "housing 30" is otherwise "*sealed*." Ex.1005, [0012].

962. Accordingly, Schima discloses that the **second magnetic device** ("magnets 10," Ex.1005) is positioned according to element [1H] "*while being spaced apart and sealed from both the* ***rotor*** ("rotor 1," Ex.1005) *and the* ***first magnetic device*** ("rotor magnets 6," Ex.1005) *of the* ***magnetically driven rotor assembly***."

x. [1I] the second magnetic device being positioned axially spaced apart from the guide surfaces of the rotor

963. Schima discloses "*the* ***second magnetic device*** *being positioned axially spaced apart from the guide surfaces of the* ***rotor***."

964. As discussed with respect to element [1D], the **rotor** comprises guide surfaces ("flow surfaces 2 and 4 vanes that produce centrifugal flow components 3 and flow components 5") to produce centrifugal flow components.

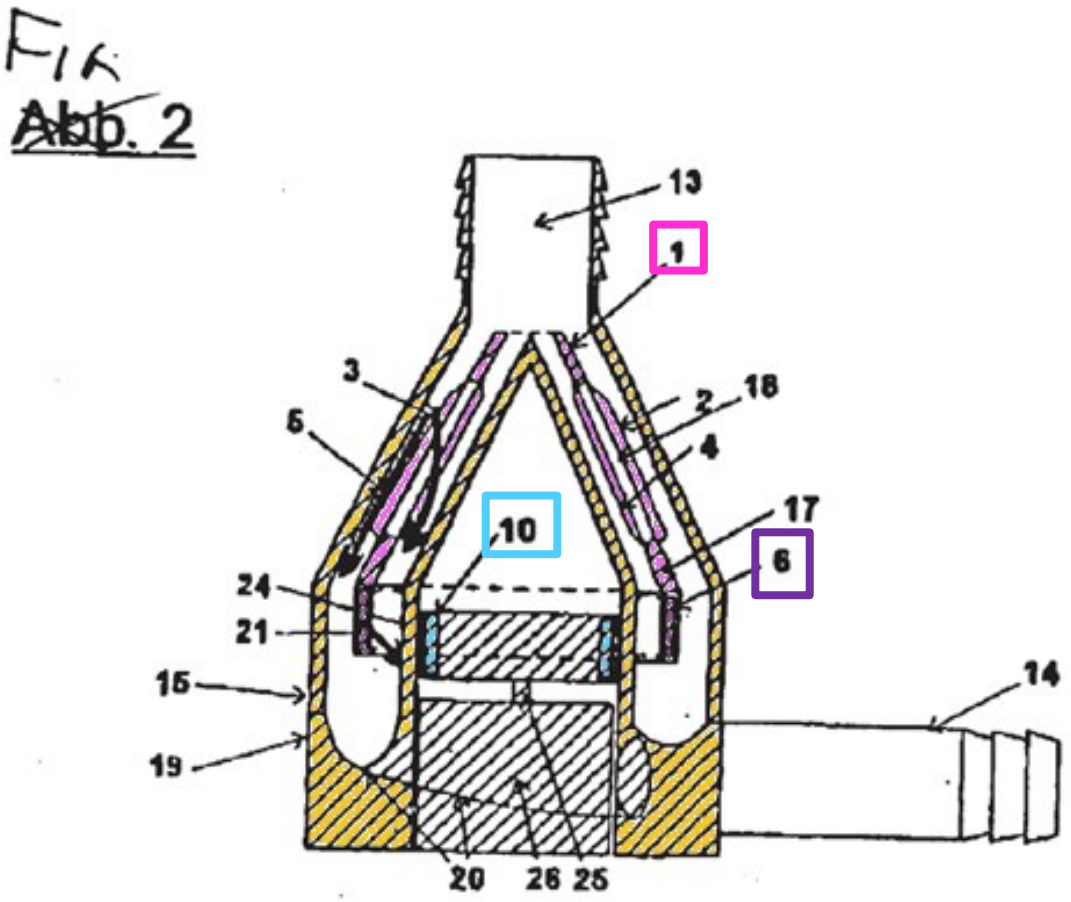
965. Schima describes that its invention relates to a rotary pump, that has a rotor 1 that is able to rotate "contact-free" ["*being positioned axially spaced apart*"] from the housing. Ex.1005, [0010], Abstract, Claim 1. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow

and dead-water areas" could create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

966. According to Schima, "therefore solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. The invention in Schima "is characterized in that the rotor has flow-control surfaces for producing centrifugal flow components and flow components directed against the housing, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for contact-free ['*being spaced apart*'] journaling and stabilizing of the rotor in the housing." Ex.1005, [0010].

967. As discussed for element [J], this contact-free spacing is accomplished in Schima by the use of the "magnets 10" within "rotating disk 24" driven by electric motor 26, which drive rotation of rotor magnets 6 by the "magnetic force 21," without the need for contact between the magnetic devices. *See supra* Section X.D.1.xi.

968. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump having magnets 10 (**light blue**) that are spaced apart and sealed from the rotor (**pink**) holding rotor magnets 6 (**purple**) by the housing 30 (**orange**):



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) *axially spaced apart from the guide surfaces of the* ***rotor*** (e.g., "rotor 1" Ex.1005, [0012]).

969. Accordingly, Schima discloses "*the* ***second magnetic device*** ("magnets 10," Ex.1005) *being positioned axially spaced apart from the guide surfaces of the* ***rotor*** ("rotor 1," Ex.1005)."

xi. [1J] a blood outflow port positioned radially adjacent the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the surrounding stationary housing in a direction substantially perpendicular to the central axis of the magnetically driven rotor assembly,

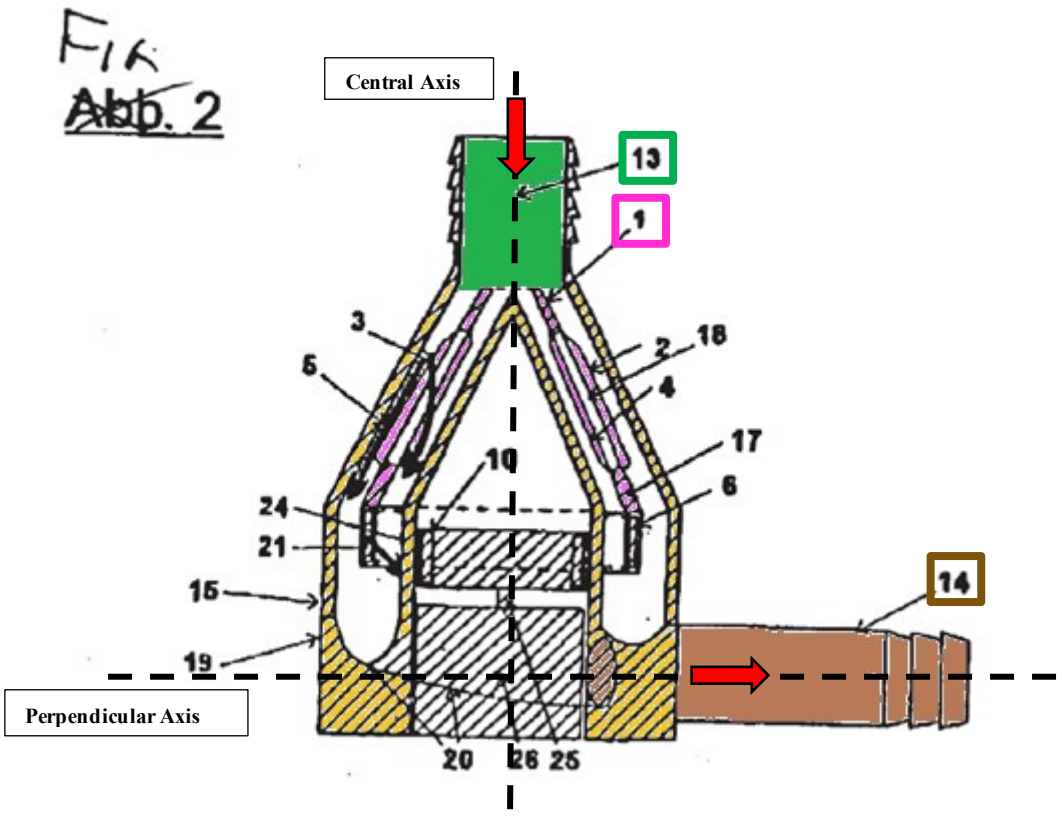
970. Schima discloses that "*a **blood outflow port** positioned radially adjacent the guide surfaces of the **rotor** such that, when the blood is driven by the **magnetically driven rotor assembly,** the blood exits the **surrounding stationary housing** in a direction substantially perpendicular to the **central axis** of the **magnetically driven rotor assembly***."

971. For example, Schima discloses that "[a] spiral-shaped outlet passage 20 in the lower housing part 19 leads to an outlet 14." Ex. 1005, [0012]. Given the "spiral shape[]" of the outlet passage leading to the "outlet 14" as shown in Figure 2, the "outlet 14" is *a **blood outflow port** positioned radially adjacent the guide surfaces of the **rotor*** ("rotor 1").

972. I note that in parallel litigation, the Patent Owner has asserted that the blood outflow port of the "HeartMate 3" is "*radially adjacent*" to a magnetically driven rotor in the same way as described above in Schima. *See* Ex. 1019, (Complaint, Ex. 13). For the purposes of my analysis, I also map the limitation that

the **blood outflow port** (e.g., "outlet 14") is "*radially adjacent*" to the guide surfaces of the **rotor** (e.g., the "rotor 1") in the same way.

973. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump showing that the outlet 14 (**brown**) is positioned radially adjacent the rotor 1 (**pink**) such that blood driven (**red** arrows) is configured to exit the housing 30 (**orange**), which includes lower part 19, conical middle part 16, and conical upper part 15, in a direction substantially perpendicular from the inlet 13 (**green**) and the central axis (**black**) of rotor 1:



Ex.1005, Fig. 2 (annotated). As discussed with respect to element [1K] below, the blood is driven by the **rotor 1** and embedded **rotor magnets 6**. Thus, this cross-sectional view shows *that blood is driven by the magnetically driven rotor* (**red** arrows moving in direction of centrifugal flow components 3 and 5) *[and] the blood exits the* ***surrounding stationary housing*** ("pump housing 30") *in a direction substantially perpendicular to the central axis* (**black**) *of the* ***magnetically driven rotor assembly*** ("rotor 1").

974. Accordingly, Schima discloses that "*a* ***blood outflow port*** ("outlet 14," Ex.1005) *positioned radially adjacent the guide surfaces of the* ***rotor*** ("rotor 1," Ex.1005) *such that, when the blood is driven by the* ***magnetically driven rotor assembly*** ("rotor 1" and "rotor magnets 6"), *the blood exits the* ***surrounding stationary housing*** ("pump housing 30," Ex.1005) *in a direction substantially perpendicular to the* ***central axis*** *of the* ***magnetically driven rotor assembly***."

xii. [1K] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing by the gap sized for passage of the blood; and

975. Schima discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** *and orient the* ***magnetically***

driven rotor assembly *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***surrounding stationary housing*** *by the gap sized for passage of the blood*."

976. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of "in response to rotation of the magnetically driven rotor, the magnetically driven rotor remains entirely spaced apart from the surrounding rotor housing **by the passage of the blood** from the inflow tube and to the blood outflow port" refers to a **hydrodynamic bearing** such that the "blood flowing" "in response to rotation of the magnetically driven rotor" **causes** the "magnetically driven rotor" to remain "entirely spaced apart from the surrounding rotor housing." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that the plain and ordinary meaning of this phrase is correct. *See* Ex.1019. However, whether this limitation is interpreted broadly (to include *exclusively* magnetic suspension) or narrowly (to require the blood flowing to cause suspension of the rotor), my interpretation would in any event be included within the Patent Owner's broader interpretation.

977. Accordingly, based on my understanding this limitation Schima discloses that the *magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** ("rotor 1") *and orient the* rotor 1, *the gap sized*

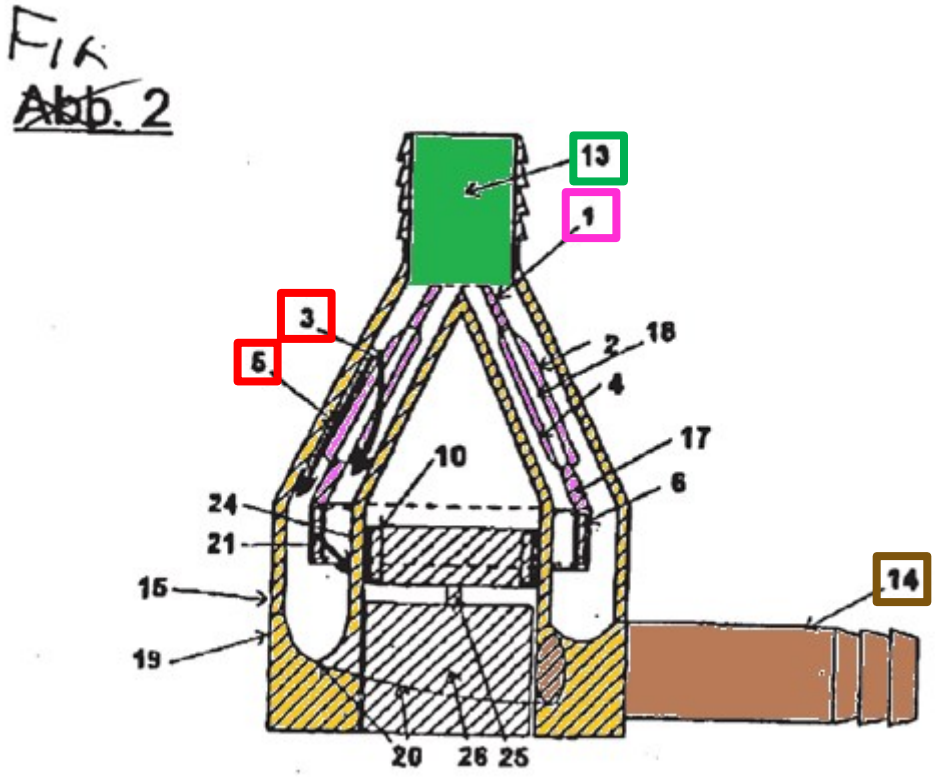
for passage of the blood causes the rotor 1 to *remain entirely spaced apart from* ***surrounding stationary housing*** ("housing 30").

978. For example, Schima describes that its contact free journaling is achieved by a hydrodynamic bearing—"[t]he rotor 1 has as flow surfaces 2 and 4 vanes that produce **centrifugal flow components** 3 and flow components 5 directed against the housing. To this end these flow surfaces 2 and 4 are formed on a conical base 17 which has rotor openings 18 for flow to the inner vanes 4. Ex.1005, [0012]. *See also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for **contact-free journaling and stabilizing of the rotor in the housing.**"); Claim 1 ("… the flow components (**5**) directed against the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

979. In particular, Schima discloses that "[t]his hollow conical **rotor 1 rotates** in a pump housing 30 ['*magneto coupling is configured to both drive rotation…and orient the magnetically driven rotor assembly*'] comprised of a housing lower part 19 with a conical middle part 16 and a hollow conical upper part

15, **centering of the hollow conical rotor in the middle part 16** [‘*the magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing*’] of the housing lower part 19 being **effected by the flow components** 5 directed against the housing [‘*by the gap sized for passage of the blood’*], this flow being preferably axially against the conical upper surface of the middle part 16. This centering can however also be wholly or additionally effected by flow components (5) directed against the housing or centrifugally (3) against the hollow conical upper part 15.” Ex.1005, [0012].

980. Figure 2 (annotated) illustrates the centrifugal flow components 3 and 5 (**red**, included in the original Figure 2) of the blood flowing from the inlet 13 (**green**) to the outlet 14 (**brown**), which are produced during by the rotation of the rotor 1 (**pink**), and directed against the housing 30 (**orange**) so as to create a “contact free journaling and stabilizing of the rotor in the housing”:



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that *magneto coupling is configured to both drive rotation…and orient the magnetically driven rotor assembly* ("**rotor 1 rotates**") *such that magnetically driven rotor assembly remains entirely spaced apart from the surrounding stationary housing* ("**housing 30**") *by the gap sized for passage of the blood* so as to create a "contact free journaling and stabilizing" when the rotor 1 is in rotation. Ex.1008, [0010], [0012].

981. Accordingly, Schima discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** ("rotor 1" and "rotor magnets 6," Ex.1005) *and orient the* ***magnetically driven rotor***

assembly *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***surrounding stationary housing*** ("pump housing 30," Ex.1005) *by the gap sized for passage of the blood*."

xiii. [1L] an external control unit configured to regulate operation of the second magnetic device based upon a control value indicative of cardiac output

982. While Schima does not explicitly disclose "*an* ***external control unit*** *configured to regulate operation of the* ***second magnetic device*** *based upon a control value indicative of cardiac output*" it would have been obvious to a POSITA at the time of the invention on February 27, 2007 to do so.

983. As I detail below in Section X.D.13 and incorporated by reference here, "*an external control unit configured to regulate operation of the second magnetic device*" is taught by Schima in view of Akamatsu-1999 because Akamatsu-1999 expressly discloses a "controller" to "operate[]" "the pump…at a fixed rotational speed" and that "[t]he pump was percutaneously driven." Ex.1006 at 5 and 7 (discussing plans to make the external controller "an implantable controller"). Figure 1 (annotated) of Akamatsu-1999 illustrates the connection of the external control unit (**lime green**) to the centrifugal pump (**blue**):

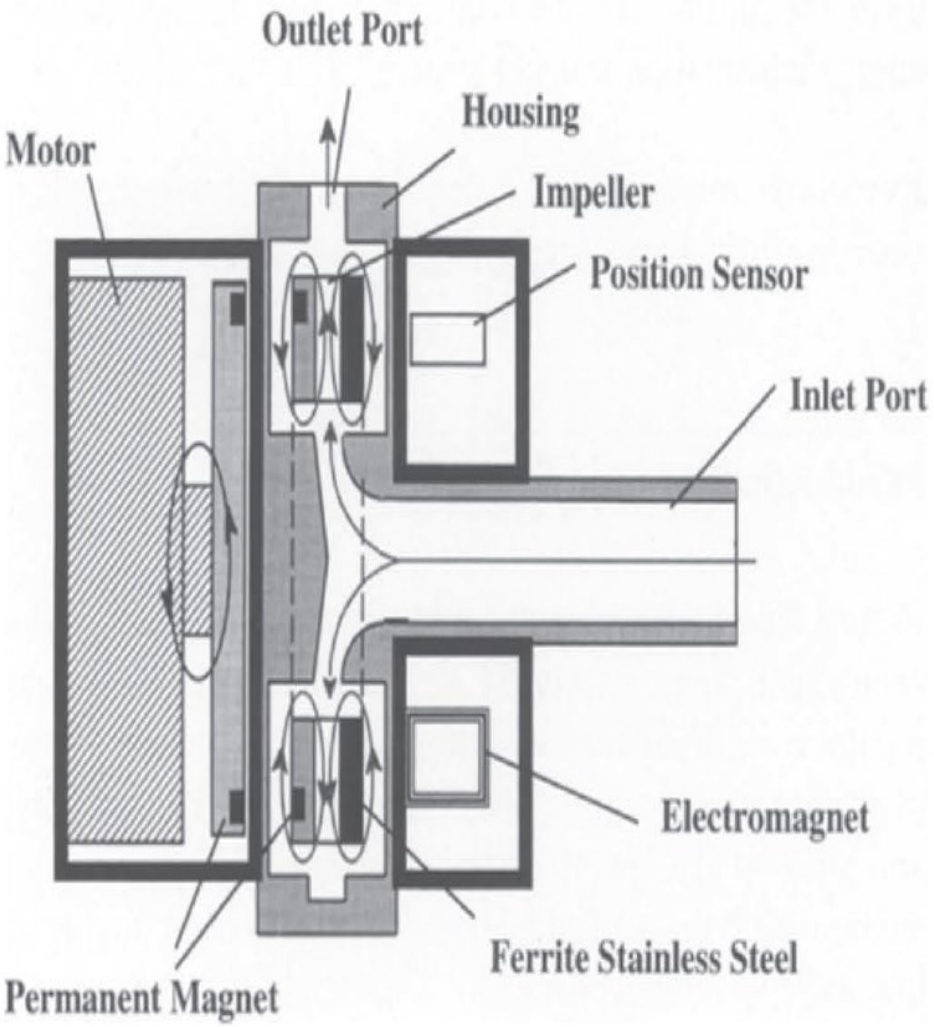


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 1 (annotated). It would have been obvious to a POSITA that Schima pump could be operated based on the teachings of Akamatsu-1999 such that Schima's "electric motor 26" (i.e., "*the second magnetic device*") could be connected to a "controller" (i.e., "*external control unit*") as taught by Akamatsu-1999. Thus, it would have been obvious to a POSITA that Schima's "electric

motor 26" could be connected to and regulated by "*an external control unit*" for the reasons explained below. *See supra* Section X.D.13

984. As discussed above and detailed below in Section X.D.13, in my opinion, it would have been obvious to combine Schima's pump with Akamatsu-1999's ***external control unit***,…to *regulate operation of the* ***second magnetic device***. *See supra* Section X.D.1.xiii. For instance, it would have been obvious because Akamatsu-1999 expressly discloses a "controller" to "operate[]" "the pump…at a fixed rotational speed" and monitor "aortic pressure and pump flow rate [which] were continuously measured." *See* Section X.D.13 (quoting Ex.1006 at 4).

985. The 077 Patent does not define a "*control value indicative of cardiac output*." In parallel litigation, however, I have been informed the Patent Owner has asserted a theory of infringement that the Heartmate 3 external control unit is configured to control the operation of the second magnetic device using a measurement value that is indicative of cardiac output, such as what Abbott calls a fixed speed or lower speed limit which is indicative of cardiac output (e.g. output as measured in liters of blood per minute. *See, e.g.*, Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of a "*control value indicative of cardiac output*."

986. Akamatsu-1999 expressly discloses the Patent Owner's apparent of a "*control value indicative of cardiac output*" through its disclosure that its "controller" "operate[s]" "the pump…at a fixed rotational speed" and that "aortic pressure and pump flow rate [which] were continuously measured." *See* Section X.D.13 (quoting Ex.1006 at 4, 5). In addition, "[t]he pump was percutaneously driven," i.e., via the electric wire through the skin. Ex.1006 at 4, 5. Put simply, the function of Akamatsu-1999's *external control unit* ("controller," Ex.1006)—which would have been obvious to combine with Schima's pump (*see supra* Section X.D.1.xiii)—was to "*control[] the second magnetic device based upon a control value indicative of cardiac output*." Ex.1006 at 4, 5 ("The pump was operated at a fixed rotational speed.").

987. Thus, the "controller" disclosed in Akamatsu-1999 is an ***external control unit*** as recited in Claim 1 which, in the combination of Schima and Akamatsu-1999, controls the ***second magnetic device*** (e.g., "magnets 10" within rotating disk 24 driven by electric motor 26," Ex.1005, [0012]) described in Schima *based upon a control value indicative of cardiac output* (e.g., "continuously measur[ing]" "aortic pressure and pump flow rate" and operating the pump at a "fixed rotational speed," Ex.1006 at 4, 5), as described in Akamatsu-1999.

988. Accordingly, Schima in view of Akamatsu-1999 renders obvious "*an **external control unit*** ("controller," Ex.1006) *configured to regulate operation of the **second magnetic device*** ("magnets 10," Ex.1005) *based upon a control value indicative of cardiac output*."

xiv. [1M] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device,

989. While Schima does not explicitly disclose the "***external control unit*** *is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**,*" it would have been obvious to a POSITA at the time of the invention on February 27, 2007 to do so.

990. As I detail below in Section X.D.13 and incorporated by reference here, "*the external control unit is connectable to the heart assist pump device for controlling the second magnetic device*" is taught by Schima in view of Akamatsu-1999 because Akamatsu-1999 expressly discloses a "controller" to "operate[]" "the pump…at a fixed rotational speed" and that "[t]he pump was percutaneously

driven." Ex.1006 at 5 and 7 (discussing plans to make the external controller "an implantable controller"). Figure 1 (annotated) of Akamatsu-1999 illustrates the connection of the external control unit (**lime green**) to the centrifugal pump (**blue**):

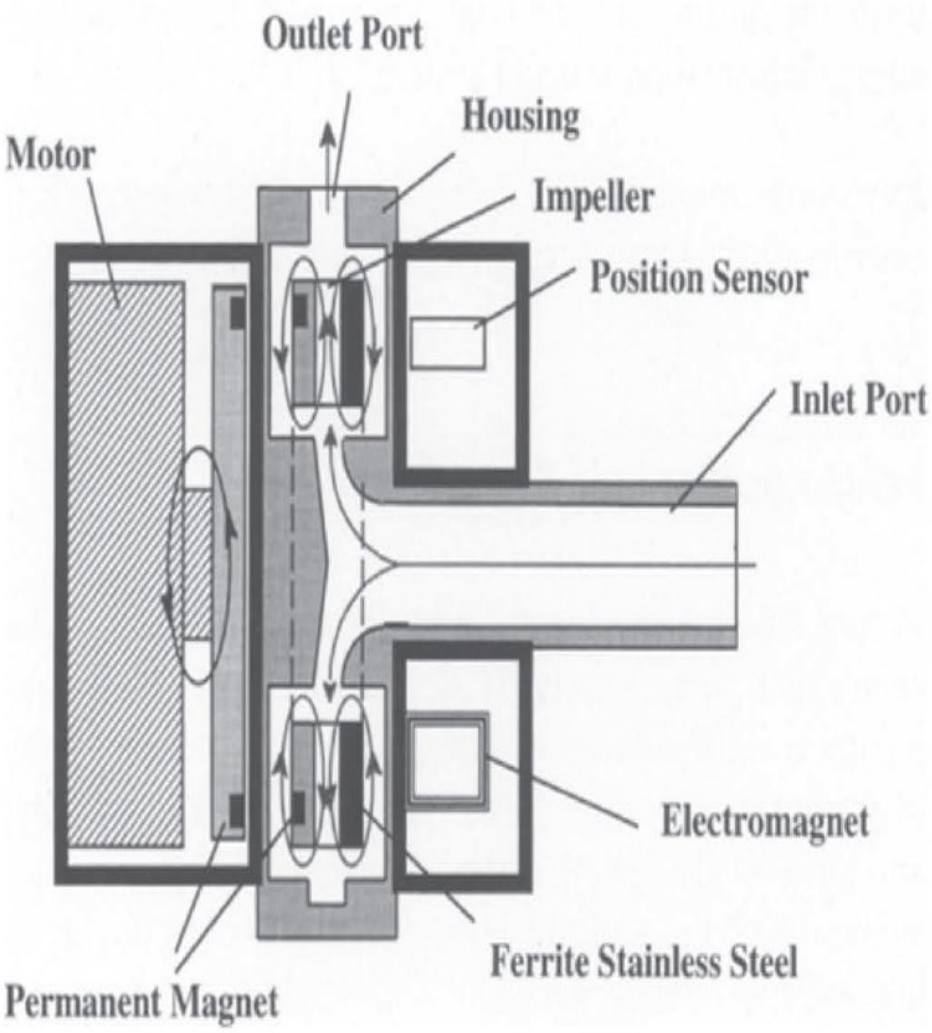


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 1 (annotated). It would have been obvious to a POSITA that Schima pump could be operated based on the teachings of Akamatsu-1999 such that

Schima's "electric motor 26" (i.e., "*the second magnetic device*") could be connected to a "controller" (i.e., "*external control unit*") as taught by Akamatsu-1999. Thus, it would have been obvious to a POSITA that Schima's "electric motor 26" could be connected to and regulated by "*an external control unit*" for the reasons explained below. *See supra* Section X.D.13.

991. Accordingly, Schima in view of Akamatsu-1999 renders obvious "*the **external control unit*** ("controller," Ex.1006) *is connectable to the **heart assist pump device*** ("pump," Ex.1005) *for controlling the **second magnetic device*** ("magnets 10," Ex.1005) *to thereby magnetically drive the rotation of the **magnetically driven rotor assembly*** ("rotor 1," Ex.1005) *via the magneto coupling with the **first magnetic device*** ("rotor magnets 6," Ex.1005)."

2. Claims 2, 3, and 4

992. Claim 4 depends from dependent claim 3 which depends from dependent Claim 2 which depends from independent Claim 1. Accordingly, I address each dependent claim in turn.

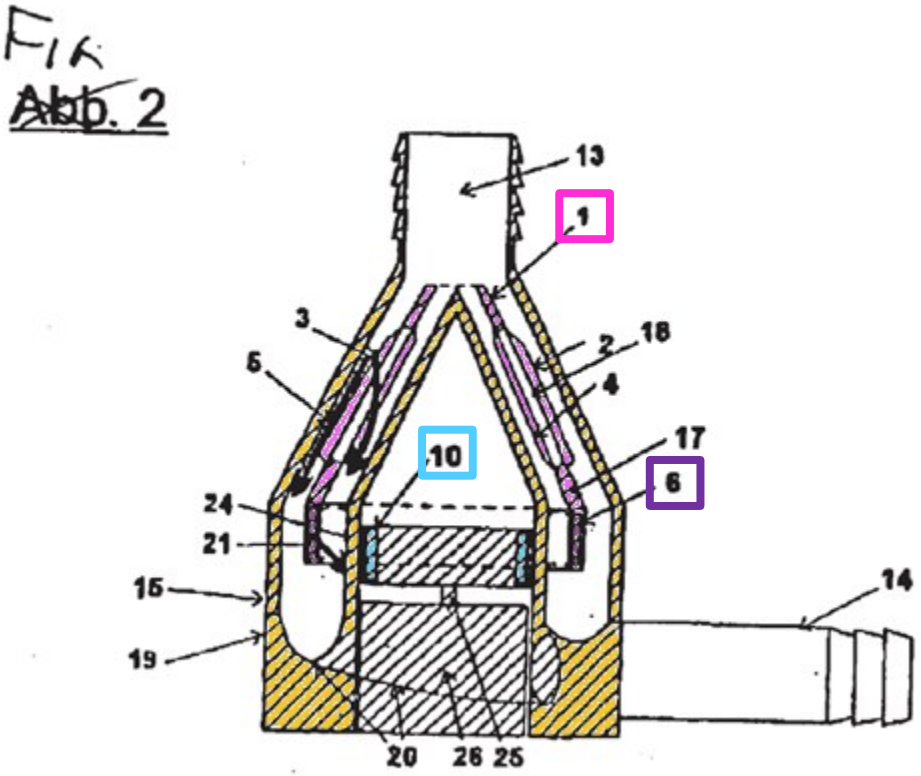
a. [2] The system of claim 1, wherein the first magnetic device is configured to be positioned between the second magnetic device and the guide surfaces of the rotor of the magnetically driven rotor assembly.

993. Schima discloses claim 2. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 2.

994. Schima discloses that "*the **first magnetic device** is configured to be positioned between the **second magnetic device** and the guide surfaces of the **rotor** of the **magnetically driven rotor assembly**.*"

995. As discussed with respect to element [1G], Schima describes a magneto coupling between the **second magnetic device** (e.g., "magnets 10" with "rotating disk 24," Ex.1005, [0013]) and the **first magnetic device** (e.g., "rotor magnets 6," Ex.1005, [0012]), which drives rotation of the **magnetically driven rotor** (e.g., "rotor 1").

996. As shown in Figure 2, the "rotor magnets 6" (**purple**) are between the "magnets 10" (**light blue**) and the "rotor 1" (**pink**) so that the "rotor magnets 6" may "transfer rotation energy" to the rotor 1 in response to the "magnetic force 21" generated by the rotation of magnets 10:



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

997. Accordingly, Schima discloses that "*the **first magnetic device*** ("rotor magnets 6," Ex.1005) *is configured to be positioned between the **second magnetic device*** ("magnets 10," Ex.1005) *and the guide surfaces of the **rotor*** ("rotor 1," Ex.1005) *of the **magnetically driven rotor assembly***."

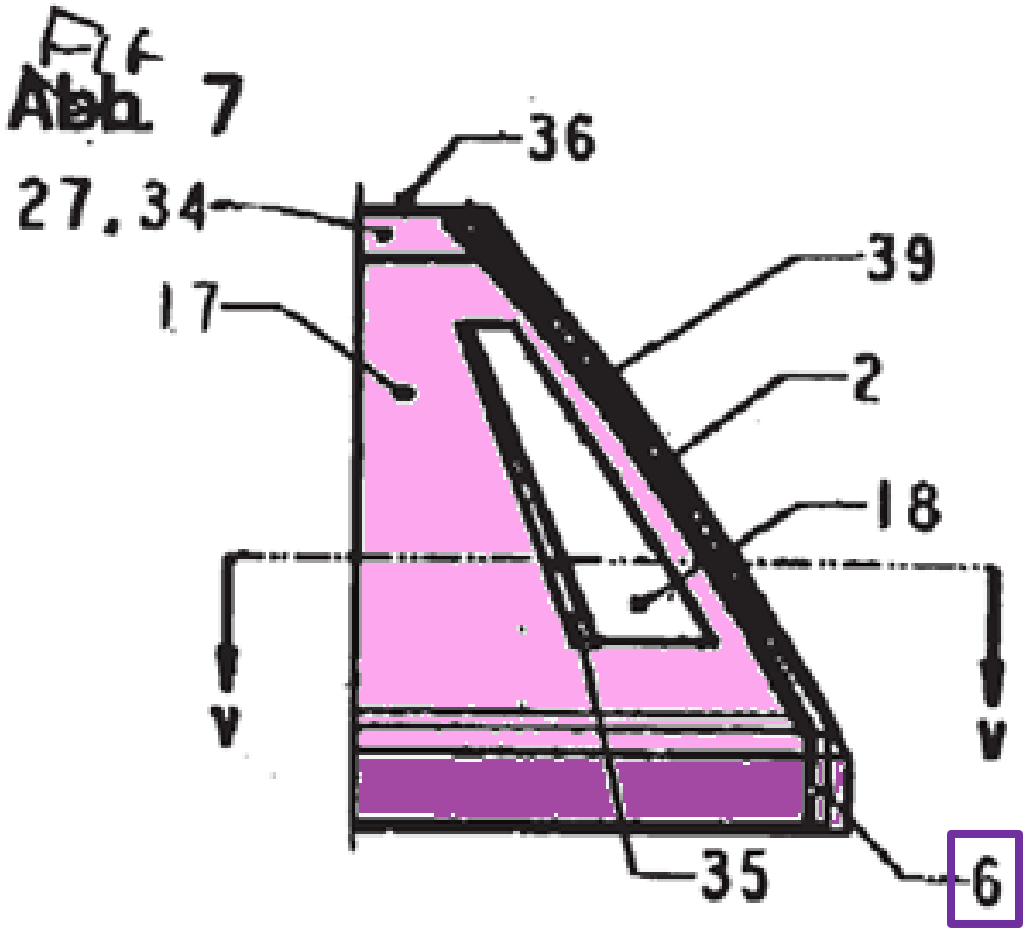
b. [3] The system of claim 2, wherein the first magnetic device is configured to rotate together with the rotor relative to the surrounding stationary housing.

998. Schima discloses and/or renders obvious claim 3. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders

obvious each and every element of claims 1 and 2. I incorporate that discussion into my analysis for claim 3.

999. Schima discloses that "*the **first magnetic device** is configured to rotate together with the **rotor** relative to the **surrounding stationary housing***."

1000. For example, Schima discloses that "[t]he rotor ['*magnetically driven rotor*'] holds rotor magnets 6 ['*first magnetic device*'] that preferably transfer rotation energy and that can be individual or formed by a continuous magnetic ring." Ex.1005, [0012]. Thus, a POSITA would understand that the "rotor magnets 6" rotate together with the "rotor 1" relative to the housing 30. For example, Figure 7 (annotated) of Schima shows a side view of the rotor 1 (**pink**) removed from the pump for clarity, which **holds** rotor magnets 6 (**purple**), which "can be formed by a continuous magnetic ring":



Ex.1005, Fig. 7 (annotated).

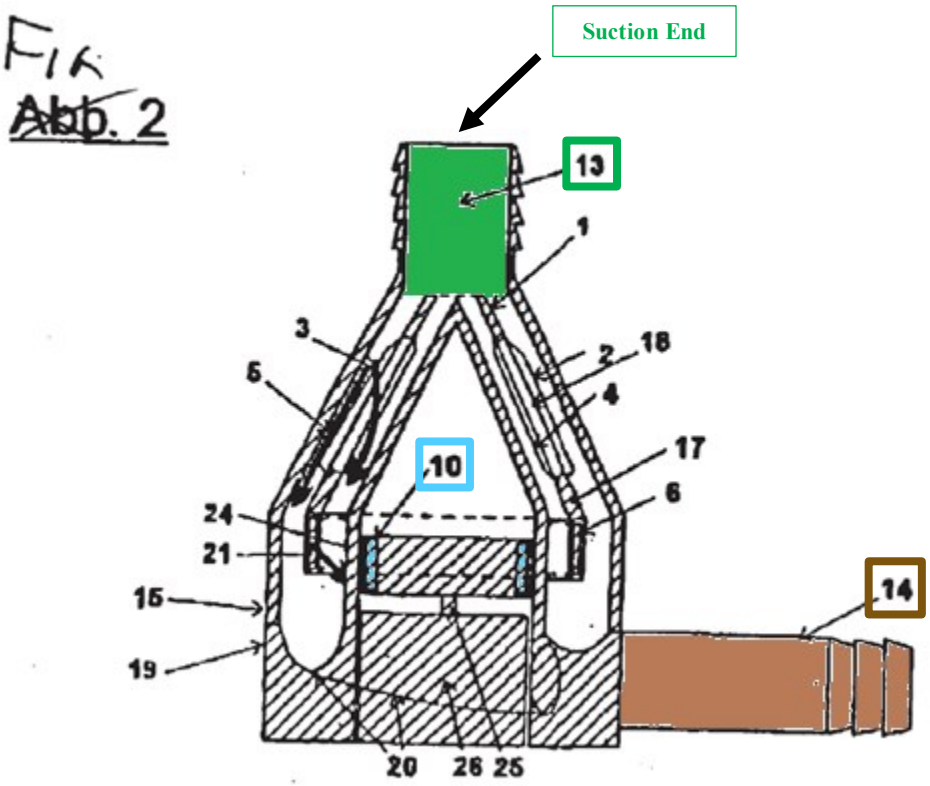
1001. Accordingly, Schima discloses that "*the **first magnetic device*** ("rotor magnets 6," Ex.1005) *is configured to rotate together with the **rotor*** ("rotor 1," Ex.1005) *relative to the **surrounding stationary housing*** ("pump housing 30," Ex.1005)."

c. [4] The system of claim 3, wherein the second magnetic device is positioned closer to the blood outflow port than to the suction end of the inflow tube.

1002. Schima discloses and/or renders obvious claim 4. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claims 1, 2, and 3. I incorporate that discussion into my analysis for claim 4.

1003. Schima in view of Akamatsu-1999 discloses and/or renders obvious that "*the **second magnetic device** is positioned closer to the **blood outflow port** than to the suction end of the **inflow tube*** ("inlet 13," Ex.1005)."

1004. For example, Figure 2 (annotated) illustrates that the magnets 10 (**light blue**) are positioned closer to the outlet 14 (**brown**) than the magnet 10 is positioned relative to the suction end of the inlet 13 (**green**):



Ex.1005, Fig. 2 (annotated). Further, Schima discloses that, unlike Figure 2 above, "the **outlet**…[can] be set higher, generally in the plane…of the rotor"), which could make the **outlet** "*positioned closer*" to **magnets 10**. Ex.1005, [0026];

1005. Accordingly, Schima in view of Akamatsu-1999 discloses and/or renders obvious that "*the **second magnetic device*** ("magnets 10," Ex.1005) *is positioned closer to the **blood outflow port*** ("outlet 14," Ex.1005) *than to the suction end of the **inflow tube*** ("inlet 13," Ex.1005)."

3. Claim 5

a. [5] The system of claim 1, wherein the magnetically driven rotor assembly is sealed from the second magnetic device and a drive source configured to regulate the operation of the second magnetic device.

1006. Schima in view of Akamatsu-1999 renders obvious claim 5. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 5.

1007. Schima discloses that "*the **magnetically driven rotor assembly** is sealed from the **second magnetic device** and a drive source configured to regulate the operation of the **second magnetic device**.*"

1008. As discussed with respect to [1H], the **rotor 1** and **rotor magnets 6** are sealed from the **magnets 10 driven by electric motor 26**.

1009. Further, as discussed with respect to elements [1L] and [1M], it would have been obvious to use an **external control unit** ("controller") such as the one described in Akamatsu-1999, as a drive source to regulate operation of the **second magnetic device** ("magnets 10" within rotating disk 24 driven by "electric motor 26").

1010. Accordingly, Schima in view of Akamatsu-1999 renders obvious that "*the **magnetically driven rotor assembly*** ("rotor 1" and "rotor magnets 6," Ex.1005)

is sealed from the ***second magnetic device*** ("magnets 10," Ex.1005) *and a drive source configured to regulate the operation of the* ***second magnetic device***."

4. Claim 7

a. [7] The system of claim 1, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

1011. Schima in view of Akamatsu-1999 renders obvious claim 7. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 7.

1012. Schima in view of Akamatsu-1999 discloses or renders obvious "*one or more sensors configured to deliver feedback signals to the* ***external control unit***."

1013. As I detail below in Section X.D.13 and incorporated by reference here, "*one or more sensors configured to deliver feedback signals*" is taught by Schima in view of Akamatsu-1999 because both Schima and Akamatsu-1999 expressly disclose *one or more sensors* and Akamatsu-1999 expressly disclose or at least renders obvious that its sensors *deliver feedback signals to the external control unit*. *See also supra* Section X.D.1.xiii.

1014. Both Schima and Akamatsu-1999 disclose the use of "position sensors" (i.e., "*one or more sensors*"). Ex.1005 at [0017] ("The position (running

characteristic) of the rotor can for example be determined by appropriate position sensors"); *see also* Ex.1005 at claim 13 (claiming embodiment using position sensors with magneto coupling drive); Ex.1006 at 4 ("The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing"). Akamatsu-1999 further teaches that these "position sensors" assist with "control[,]" and a POSITA would have understood that requires the "position sensors" to send feedback signals to the controller "to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also supra* Section X.D.1.xiii. Thus, it would have been obvious to a POSITA that positions sensors ("*one or more sensors*") disclosed by both Schima and Akamatsu-1999 could "*deliver feedback signals*" to the Akamatsu-1999 "controller" ("*to the external control unit"*) in the Schima/Akamatsu combination.

1015. Further, as I explain below in Section X.D.13, using these one or more sensors to provide feedback signals to an external controller would have required merely applying a known technique of signal processing in a known way using prior art equipment, such as sensors and an external "controller." *See infra* Section X.D.13. The resultant combination of Schima and Akamatsu-1999 would have been predictable, and a POSITA would have a reasonable expectation of success because using sensors in heart assist pump devices was well known in the field.

Implementing the combination would have been well within the ordinary skillset of a POSITA.

1016. Accordingly, Schima in view of Akamatsu-1999 discloses "*one or more sensors* ("position sensors," Ex.1005) *configured to deliver feedback signals to the* ***external control unit*** ("controller," Ex.1006)."

5. Claim 10

a. [10] The system of claim 1, wherein the heart assist pump device is a catheter device.

1017. Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious claim 10. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 1. I incorporate that discussion into my analysis for claim 10.

1018. Schima in view of Akamatsu-1999 discloses and/or renders obvious that "*the* ***heart assist pump device*** *is a catheter device*."

1019. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See, e.g.*, Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "catheter device."

1020. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], combination of Schima and Akamatsu includes the "rotary pump" disclosed in Schima that includes a "catheter" which is an **inflow tube** (e.g., "inlet 13," Ex.1005) that is "inserted into the left ventricle through a cuff sutured to the left ventricular apex" as described in Akamatsu. Ex.1006 at 4; *see supra* Section X.D.1.ii.

1021. Accordingly, Schima in view of Akamatsu-1999 discloses that "*the **heart assist pump device*** ("pump," Ex.1005) *is a catheter device*."

6. Claim 16

1022. As demonstrated below, the scope of claim 16 substantially overlaps with claim 1 and is rendered obvious for the same reasons. For instance, the "surrounding stationary housing" of claim 1 is essentially the same as the "chamber walls at least partially defining a chamber" of claim 16. Similarly, because the "inflow tube" and "central axis" of claim 1 are aligned, the claimed "inflow axis" of claim 16 is rendered obvious for the same reasons.

a. [16pre] A system for assisting blood circulation of a heart, the system comprising

1023. Schima discloses "*a system for assisting blood circulation of a **heart***."

1024. This element is invalid for the same reasons discussed above in [1PRE], thus, I incorporate that discussion into my analysis here.

1025. Accordingly, Schima discloses "a system for assisting blood circulation of a **heart**."

b. [16a] a heart assist pump device deliverable to the heart and comprising: an inflow tube defining a blood inflow path along an inflow axis and being insertable into a left ventricle;

1026. Schima discloses "*a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**.*"

1027. This element is invalid for the same reasons discussed above in [1A] and [1B], thus, I incorporate that discussion into my analysis here.

1028. Accordingly, Schima, or Schima/Akamatsu-1999, discloses "a **heart assist pump device** deliverable to the **heart** and comprising: an **inflow tube defining a blood inflow path** along an **inflow axis** and being insertable into **a left ventricle**."

c. [16b] chamber walls at least partially defining a chamber to receive blood from the inflow tube;

1029. Schima discloses "*chamber walls at least partially defining a chamber to receive blood from the inflow tube.*"

1030. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

1031. Accordingly, Schima discloses "***chamber walls at least partially defining a chamber*** *to receive blood from the* ***inflow tube***."

d. [16c] a magnetically driven rotor assembly configured to be axially aligned with the inflow axis and comprising a first magnetic device

1032. Schima discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

1033. This element is invalid for the same reasons discussed above in [1B] and [1C], thus, I incorporate that discussion into my analysis here.

1034. Accordingly, Schima, or Schima/Akamatsu-1999, discloses "*a* ***magnetically driven rotor assembly*** *configured to be axially aligned with the* ***inflow axis*** *and comprising a* ***first magnetic device***."

e. [16d] that [the first magnetic device] is rigidly coupled to and axially adjacent to a rotor

1035. Schima discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

1036. This element is invalid for the same reasons discussed above in [1C], thus, I incorporate that discussion into my analysis here.

1037. Accordingly, Schima discloses that a **first magnetic device** "*is rigidly coupled to and axially adjacent to a* ***rotor***."

f. [16e] [the rotor] having guide surfaces to produce centrifugal flow components,

1038. Schima discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

1039. This element is invalid for the same reasons discussed above in [1D], thus, I incorporate that discussion into my analysis here.

1040. Accordingly, Schima discloses the **rotor** "*having guide surfaces to produce centrifugal flow components*."

g. [16f] the rotor and the first magnetic device of the magnetically driven rotor assembly being rotatable within the chamber about an axis of rotation

1041. Schima discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

1042. This element is invalid for the same reasons discussed above in [1E], thus, I incorporate that discussion into my analysis here.

1043. Accordingly, Schima discloses "*the **rotor** and the **first magnetic device** of the **magnetically driven rotor assembly** being rotatable within the **chamber** about an axis of rotation*."

h. [16g] [the axis of rotation is] aligned with the inflow axis to drive the blood flowing from the inflow tube;

1044. Schima discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

1045. This element is invalid for the same reasons discussed above in [1B] and [1E], thus, I incorporate that discussion into my analysis here.

1046. Accordingly, Schima, or Schima/Akamatsu-1999, discloses that the axis of rotation is "*aligned with the **inflow axis** to drive the blood flowing from the **inflow tube***."

i. [16h] a magnetic drive system comprising a second magnetic device axially aligned with the inflow axis

1047. Schima discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

1048. This element is invalid for the same reasons discussed above in [1G], thus, I incorporate that discussion into my analysis here. Additionally, Schima discloses that "the drive can be a disk-rotor motor" having "imbedded magnets 10 ('***second magnetic device***')," and thus, Schima discloses a "*magnetic drive system.*"

1049. Accordingly, Schima discloses "*a **magnetic drive system** comprising a **second magnetic device** axially aligned with the **inflow axis***."

j. [16i] and spaced apart from the magnetically driven rotor assembly such that a wall of the chamber walls defining the chamber is positioned between the magnetically driven rotor assembly and the second magnetic device,

1050. Schima discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

1051. This element is invalid for the same reasons discussed above in [1K] and [2], thus, I incorporate that discussion into my analysis here.

1052. Accordingly, Schima discloses that the **second magnetic device** is "*spaced apart from the **magnetically driven rotor assembly** such that **a wall of the chamber walls defining the chamber** is positioned between the **magnetically driven rotor assembly** and the **second magnetic device**.*"

k. [16j] a blood outflow port positioned radially outward of the guide surfaces of the rotor such that, when the blood is driven by the magnetically driven rotor assembly, the blood exits the chamber in a direction substantially perpendicular to the inflow axis,

1053. Schima discloses "*a **blood outflow port** positioned radially outward of the guide surfaces of the **rotor** such that, when the blood is driven by the*

magnetically driven rotor assembly, *the blood exits the* ***chamber*** *in a direction substantially perpendicular to the* ***inflow axis***."

1054. This element is invalid for the same reasons discussed above in [1H], thus, I incorporate that discussion into my analysis here.

1055. Accordingly, Schima discloses "*a* ***blood outflow port*** *positioned radially outward of the guide surfaces of the* ***rotor*** *such that, when the blood is driven by the* ***magnetically driven rotor assembly***, *the blood exits the* ***chamber*** *in a direction substantially perpendicular to the* ***inflow axis***."

l. [16k] wherein the magneto coupling is configured to both drive rotation of the magnetically driven rotor assembly and orient the magnetically driven rotor assembly such that the magnetically driven rotor assembly remains entirely spaced apart from the chamber walls by a gap sized for passage of the blood; and

1056. Schima discloses that "*the magneto coupling is configured to both drive rotation of the* ***magnetically driven rotor assembly*** *and orient the* ***magnetically driven rotor assembly*** *such that the* ***magnetically driven rotor assembly*** *remains entirely spaced apart from the* ***chamber walls*** *by a gap sized for passage of the blood.*"

1057. This element is invalid for the same reasons discussed above in [1J], thus, I incorporate that discussion into my analysis here.

1058. Accordingly, Schima discloses that "*the magneto coupling is configured to both drive rotation of the **magnetically driven rotor assembly** and orient the **magnetically driven rotor assembly** such that the **magnetically driven rotor assembly** remains entirely spaced apart from the **chamber walls** by a gap sized for passage of the blood.*"

m. [16l] an external control unit configured to control operation of the second magnetic device based on a control value indicative of cardiac output

1059. Schima discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

1060. This element is invalid for the same reasons discussed above in [1M], thus, I incorporate that discussion into my analysis here.

1061. Accordingly, Schima/Akamatsu-1999, discloses "*an **external control unit** configured to control operation of the **second magnetic device** based on a control value indicative of cardiac output*."

n. [16m] wherein the external control unit is connectable to the heart assist pump device for controlling the second magnetic device to thereby magnetically drive the rotation of the magnetically driven rotor assembly via the magneto coupling with the first magnetic device.

1062. Schima discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

1063. This element is invalid for the same reasons discussed above in [1L], thus, I incorporate that discussion into my analysis here.

1064. Accordingly, Schima/Akamatsu-1999, discloses that "*the **external control unit** is connectable to the **heart assist pump device** for controlling the **second magnetic device** to thereby magnetically drive the rotation of the **magnetically driven rotor assembly** via the magneto coupling with the **first magnetic device**.*"

7. Claim 17

1065. Claim 17, depends from independent Claim 16. Accordingly, I address this dependent claim herein.

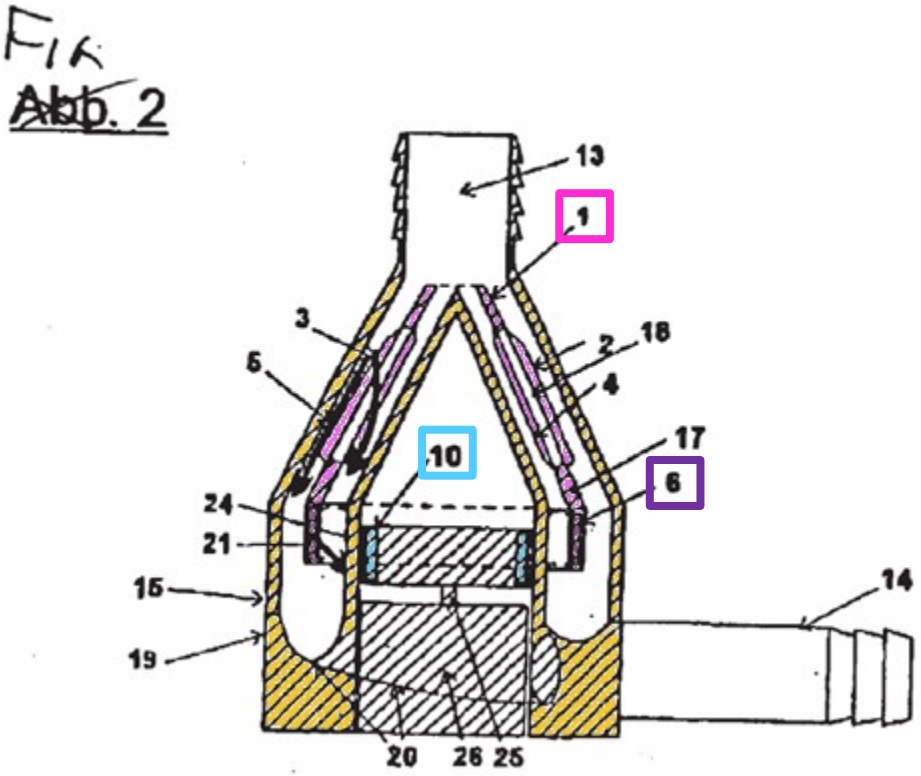
a. [17] The system of claim 16, wherein the first magnetic device is rigidly coupled to the rotor of the magnetically driven rotor assembly at a position between the second magnetic device and the rotor.

1066. Schima discloses and/or renders obvious claim 17. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 17.

1067. Schima discloses that "*the **first magnetic device** is rigidly coupled to the **rotor** of the **magnetically driven rotor assembly** at a position between the **second magnetic device** and the **rotor**.*"

1068. As discussed with respect to element [1J], Schima describes a magneto coupling between the **second magnetic device** (e.g., "magnets 10" with "rotating disk 24," Ex.1005, [0013]) and the **first magnetic device** (e.g., "rotor magnets 6," Ex.1005, [0012]), which drives rotation of the **magnetically driven rotor** (e.g., "rotor 1").

1069. As shown in Figure 2, the "rotor magnets 6" (**purple**) are between the "magnets 10" (**light blue**) and the "rotor 1" (**pink**) so that the "rotor magnets 6" may "transfer rotation energy" to the rotor 1 in response to the "magnetic force 21" generated by the rotation of magnets 10:



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

1070. Accordingly, Schima discloses that "*the **first magnetic device*** ("rotor magnets 6," Ex.1005) *is rigidly coupled to the **rotor** of the **magnetically driven rotor assembly*** ("rotor 1," Ex.1005) *at a position between the **second magnetic device*** ("magnets 10," Ex.1005) *and the **rotor***."

8. Claims 18, 19, 20, and 21

1071. Claim 21 depends from dependent claim 20 which depends from dependent claim 19 which depends from dependent claim 18 which depends from independent claim 16. Accordingly, I address each dependent claim in turn.

a. [18] The system of claim 16, wherein said gap sized for passage of the blood is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor assembly.

1072. Schima discloses and/or renders obvious claim 18. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 18.

1073. Schima discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the **second magnetic device** drives the rotation of the **magnetically driven rotor***."

1074. As discussed in Section VII.A.2, a POSITA as of February 27, 2007 would have understood the plain and ordinary meaning of a "gap sized for **passage of the blood** is configured to be occupied by the blood when the second magnetic device drives the rotation of the magnetically driven rotor" refers to a **hydrodynamic bearing** such that the blood flowing in response to rotation of the magnetically driven rotor **causes** the "gap sized sized for passage of the blood…to be occupied by the blood." *See* Section VII.A.2. For the purposes of my analysis in this Ground, I assume that the plain and ordinary meaning of this phrase is correct. *See* Ex.1019. However, whether this limitation is interpreted broadly (to include

exclusively magnetic suspension) or narrowly (to require the blood flowing to cause suspension of the rotor), my interpretation would in any event be included within the Patent Owner's broader interpretation.

1075. Accordingly, based on my understanding this limitation Schima discloses that the *second magnetic device drives the rotation of the* ***magnetically driven rotor assembly*** ("rotor 1") and the *gap sized for passage of the blood* causes the rotor 1 to remain entirely spaced apart from **surrounding stationary housing** ("housing 30").

1076. For example, Schima describes that its contact free journaling is achieved by a hydrodynamic bearing—"[t]he rotor 1 has as flow surfaces 2 and 4 vanes that produce **centrifugal flow components** 3 and flow components 5 directed against the housing. To this end these flow surfaces 2 and 4 are formed on a conical base 17 which has rotor openings 18 for flow to the inner vanes 4. Ex.1005, [0012]. *See also* Ex.1005, [0010] ("The invention is characterized in that the rotor has flow-control surfaces for producing **centrifugal flow components and flow components directed against the housing**, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for **contact-free journaling and stabilizing of the rotor in the housing.**"); Claim 1 ("… the flow components (**5**) directed against

the housing serving mainly for **contact free journaling and stabilizing of the rotor in the housing**").

1077. Accordingly, Schima discloses that a "*gap sized for passage of the blood is configured to be occupied by the blood when the* ***second magnetic device*** *drives the rotation of the* ***magnetically driven rotor assembly*** ("rotor 1," Ex.1005)."

b. [19] The system of claim 18, wherein the gap surrounds the magnetically driven rotor assembly.

1078. Schima discloses claim 19. I have already explained how Schima discloses each and every element of claim 18. I incorporate that discussion into my analysis for claim 19.

1079. Schima discloses that "*the gap surrounds the* ***magnetically driven rotor assembly***."

1080. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the* ***magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

1081. Accordingly, Schima discloses that "*the gap surrounds the* ***magnetically driven rotor assembly***."

c. [20] The system of claim 18, wherein at least part of the gap extends radially outward from the magnetically driven rotor assembly.

1082. Schima discloses claim 20. I have already explained how Schima discloses each and every element of claims 18 and 19. I incorporate that discussion into my analysis for claim 20.

1083. Schima discloses that "*at least part of the gap extends radially outward from the* ***magnetically driven rotor assembly***."

1084. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the* ***magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

1085. Accordingly, Schima discloses that "*at least part of the gap extends radially outward from the* ***magnetically driven rotor assembly***."

d. [21] The system of claim 20, wherein at least part of the gap extends along a face of the magnetically driven rotor assembly that is axially opposite from the inflow tube.

1086. Schima discloses claim 21. I have already explained how Schima discloses each and every element of claims 18, 19, and 20. I incorporate that discussion into my analysis for claim 21.

1087. Schima discloses that "*at least part of the gap extends along a face of the **magnetically driven rotor assembly** that is axially opposite from the **inflow tube***."

1088. This element is invalid for the same reasons discussed above in [1F] and [1K] and [19]—i.e., the gap extends entirely surrounding *the **magnetically driven rotor assembly***—thus, I incorporate that discussion into my analysis here.

1089. Accordingly, Schima discloses that "*at least part of the gap extends along a face of the **magnetically driven rotor assembly** that is axially opposite from the **inflow tube***."

9. Claims 22 and 23

1090. Claim 19, depends from dependent Claim 18. Accordingly, I address this dependent claim herein.

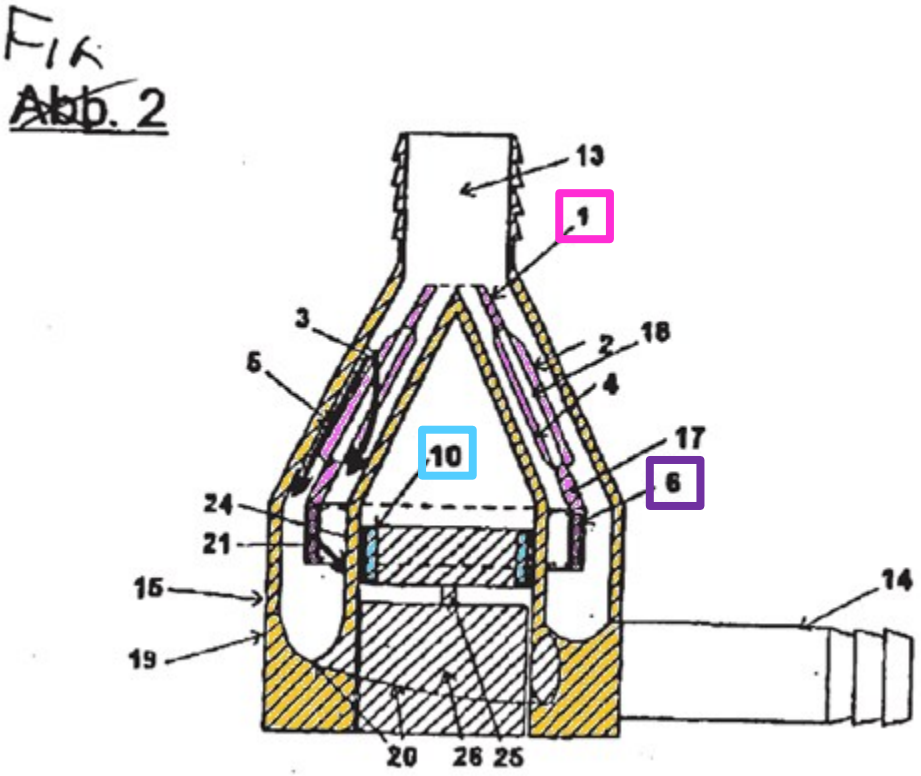
a. [22] The system of claim 16, wherein the chamber is a first chamber within which the magnetically driven rotor assembly is positioned, and the magnetic drive system is positioned within a second chamber sealed from the first chamber.

1091. Schima discloses and/or renders obvious claim 22. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 22.

1092. Schima discloses that "*the **chamber** is a first chamber within which the **magnetically driven rotor assembly** is positioned, and the magnetic drive system is positioned within a **second chamber** sealed from the **first chamber**.*"

1093. As discussed with respect to element [1J], Schima describes a magneto coupling between the **second chamber** (e.g., "magnets 10" with "rotating disk 24," Ex.1005, [0013]) and the **first chamber** (e.g., "rotor magnets 6," Ex.1005, [0012]), which drives rotation of the **magnetically driven rotor assembly** (e.g., "rotor 1").

1094. As shown in Figure 2, the "rotor magnets 6" (**purple**) are between the "magnets 10" (**light blue**) and the "rotor 1" (**pink**) so that the "rotor magnets 6" may "transfer rotation energy" to the rotor 1 in response to the "magnetic force 21" generated by the rotation of magnets 10:



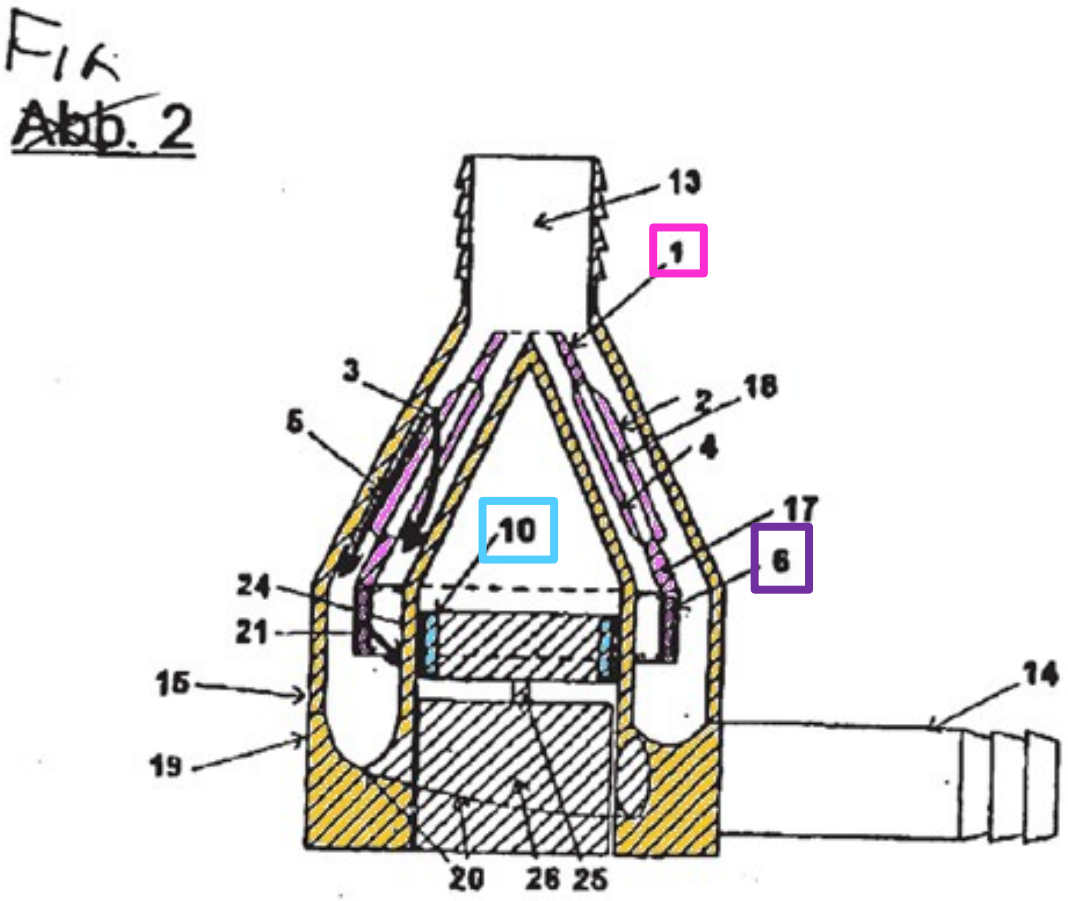
Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

1095. Schima describes that its invention relates to a rotary pump, that has a rotor 1 that is able to rotate "contact-free" ["*sealed*"] from the housing. Ex.1005, [0010], Abstract, Claim 1. Indeed, existing "conventional axle-type pumps" used at the time had an "axle…mounted in a standard seal, for example in a needle bearing in the pump chamber, so as to produce regions of high shear, friction and also often of low flow velocity near the axle." Ex.1005, [0003]. However, because of the seal required for those pumps, "low-flow and dead-water areas" could create deposits, which is "referred to as thrombosis- or clot-forming." Ex.1005, [0002].

1096. According to Schima, "therefore solutions have been suggested to provide pumps without axles or mechanical bearings." Ex.1005, [0004]. The invention in Schima "is characterized in that the rotor has flow-control surfaces for producing centrifugal flow components and flow components directed against the housing, the centrifugal flow components serving mainly for producing the externally effective throughput and the flow components directed against the housing serving mainly for contact-free ['*being spaced apart*'] journaling and stabilizing of the rotor in the housing." Ex.1005, [0010].

1097. As discussed for element [1G], this contact-free spacing is accomplished in Schima by the use of the "magnets 10" within "rotating disk 24" driven by electric motor 26, which drive rotation of rotor magnets 6 by the "magnetic force 21," without the need for contact between the magnetic devices. *See supra* Section X.D.1.viii.

1098. Figure 2 (annotated) of Schima illustrates a cross-sectional view of the pump having magnets 10 (**light blue**) that are spaced apart and sealed from the rotor (**pink**) holding rotor magnets 6 (**purple**) by the housing 30 (**orange**):



Ex.1005, Fig. 2 (annotated). Thus, this cross-sectional view shows that the ***second magnetic device*** (e.g., "magnets 10" within "rotating disk 24," Ex.1005, [0013]) *sealed from the* ***first chamber*** (e.g., "rotor magnets 6", Ex.1005, [0012]).

1099. Accordingly, Schima discloses that "*the* ***chamber*** *is a first chamber within which the* ***magnetically driven rotor assembly*** ("rotor 1," Ex.1005) *is positioned, and the magnetic drive system is positioned within a* ***second chamber*** ("magnets 10," Ex.1005) *sealed from the* ***first chamber*** ("rotor magnets 6," Ex.1005)*."*

b. [23] The system of claim 22, wherein said wall of the chamber walls separates the first chamber from the second chamber.

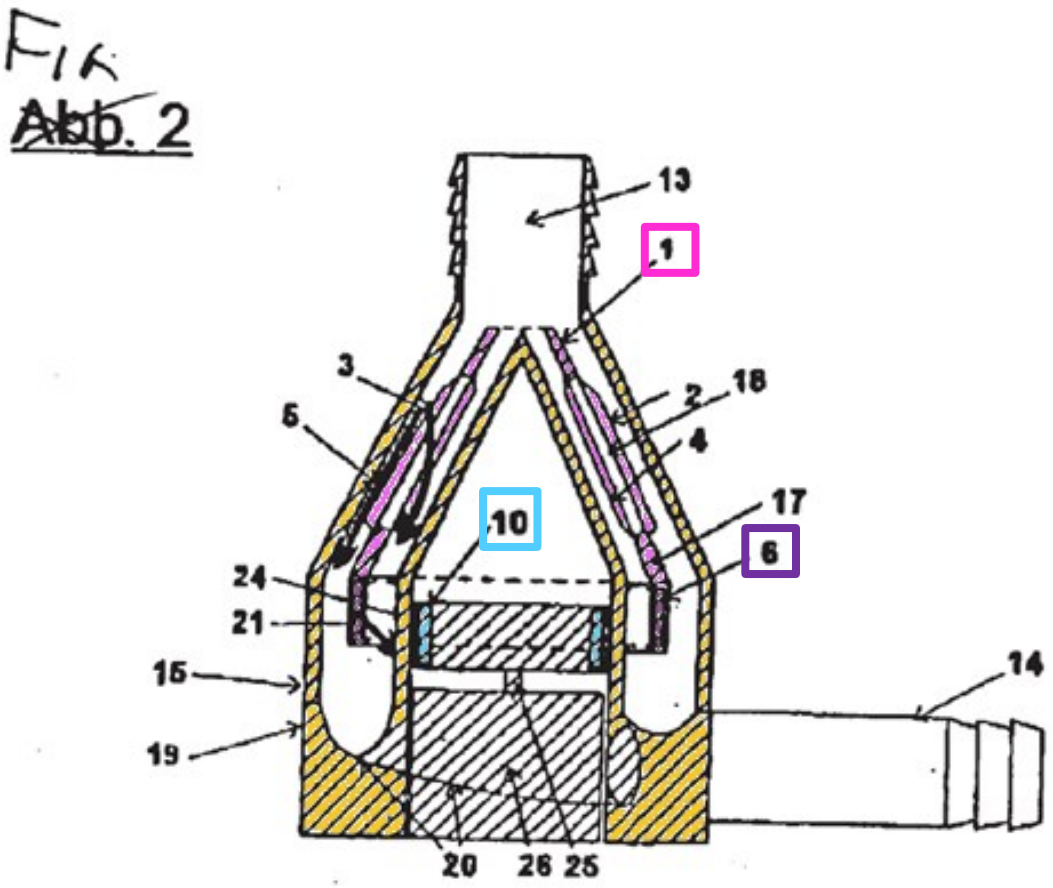
1100. Schima discloses and/or renders obvious claim 23. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 22. I incorporate that discussion into my analysis for claim 23.

1101. Schima discloses that a "*wall of the chamber walls separates the **first chamber** from the **second chamber***." As discussed with respect to element [1E], Schima discloses that the centrifugal pump includes a "housing 30" that is a "***surrounding stationary housing***" as recited in claim 1. *See supra* Section X.D.1.vi; Ex.1005, [0012], Fig. 2.

1102. Schima describes that its invention relates to a rotary pump, that has a rotor 1 that is able to rotate "contact-free" from the housing. Ex.1005, [0010], Abstract, Claim 1. As discussed for element [1G], this is accomplished in Schima by the use of the "magnets 10" within "rotating disk 24" driven by electric motor 26, which drive rotation of rotor magnets 6 by the "magnetic force 21," without the need for contact between the magnetic devices.

1103. Thus, as shown in Figure 2, the housing 30 (**orange**, which is also described with respect to the embodiment of Figure 1 though not labeled here)

includes the "conical middle part 16," which therefore comprises a "sealing wall" between the first "rotor magnets 6" (**purple**) and the "magnets 10" (**light blue**):



Ex.1005, Fig. 2 (annotated); *see also* Fig. 1.

1104. Accordingly, Schima discloses that a "*wall of the chamber walls separates the* ***first chamber*** ("rotor magnets 6," Ex.1005) *and the* ***second chamber*** ("magnets 10," Ex.1005)."

10. Claim 24

a. [24] The system of claim 16, wherein the first magnetic device comprises a permanent magnet.

1105. Schima discloses claim 24. I have already explained how Wampler-169 discloses each and every element of claim 16. I incorporate that discussion into my analysis for claim 24.

1106. Schima discloses that "*the **first magnetic device** comprises a permanent magnet*."

1107. This element is invalid for the same reasons discussed above in [1C] and [16C], thus, I incorporate that discussion into my analysis here.

1108. Accordingly, Schima discloses that "*the **first magnetic device** comprises a permanent magnet*."

11. Claim 26

a. [26] The system of claim 16, further comprising one or more sensors configured to deliver feedback signals to the external control unit.

1109. Schima discloses and/or renders obvious claim 26. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 26.

1110. Schima in view of Akamatsu-1999 discloses or renders obvious "*one or more sensors configured to deliver feedback signals to the* ***external control unit***."

1111. As I detail below in Section X.D.13 and incorporated by reference here, "*providing feedback signals to the external control unit from one or more sensors*" is taught by Schima in view of Akamatsu-1999 because both Schima and Akamatsu-1999 expressly disclose *one or more sensors* and Akamatsu-1999 expressly disclose or at least renders obvious that its sensors *deliver feedback signals to the external control unit*. *See also supra* Section X.D.1.xiii.

1112. Both Schima and Akamatsu-1999 disclose the use of "position sensors" (i.e., "*one or more sensors*"). Ex.1005 at [0017] ("The position (running characteristic) of the rotor can for example be determined by appropriate position sensors"); *see also* Ex.1005 at claim 13 (claiming embodiment using position sensors with magneto coupling drive); Ex.1006 at 4 ("The electric current of the electromagnet is controlled by using three position sensors to maintain the impeller free-floating at the center of the pump housing"). Akamatsu-1999 further teaches that these "position sensors" assist with "control[,]" and a POSITA would have understood that requires the "position sensors" to send feedback signals to the controller "to maintain the impeller free-floating at the center of the pump housing." Ex.1006 at 4; *see also supra* Section X.D.1.xiii. Thus, it would have been obvious

to a POSITA that positions sensors ("*one or more sensors*") disclosed by both Schima and Akamatsu-1999 could "*deliver feedback signals*" to the Akamatsu-1999 "controller" ("*to the external control unit"*) in the Schima/Akamatsu combination.

1113. Further, as I explain below in Section X.D.13, using these one or more sensors to provide feedback signals to an external controller would have required merely applying a known technique of signal processing in a known way using prior art equipment, such as sensors and an external "controller." *See infra* Section X.D.13. The resultant combination of Schima and Akamatsu-1999 would have been predictable, and a POSITA would have a reasonable expectation of success because using sensors in heart assist pump devices was well known in the field. Implementing the combination would have been well within the ordinary skillset of a POSITA.

1114. Accordingly, Schima in view of Akamatsu-1999 discloses "*one or more sensors* ("position sensors," Ex.1005) *configured to deliver feedback signals to the* ***external control unit*** ("controller," Ex.1006)."

12. Claim 28

a. [28] The system of claim 16, wherein the heart assist pump device is a catheter device.

1115. Schima discloses and/or renders obvious claim 28. I have already explained how Schima alone or in view of Akamatsu-1999 discloses and/or renders

obvious each and every element of claim 16. I incorporate that discussion into my analysis for claim 28.

1116. Schima in view of Akamatsu-1999 discloses and/or renders obvious that "*the **heart assist pump device** is a catheter device*."

1117. The 077 Patent does not define the term "catheter device." However, I have been informed that in parallel litigation, the Patent Owner has asserted a theory of infringement that the Heartmate 3 heart assist pump device is a catheter device because it includes a catheter, which Abbott calls an Inflow Cannula. *See, e.g.*, Ex.1019 (Complaint, Ex. 13). For the purposes of my analysis, I adopt that construction of "catheter device."

1118. Based on Patent Owner's construction, for the same reasons discussed with respect to element [1A], combination of Schima and Akamatsu includes the "rotary pump" disclosed in Schima that includes a "catheter" which is an **inflow tube** (e.g., "inlet 13," Ex.1005) that is "inserted into the left ventricle through a cuff sutured to the left ventricular apex" as described in Akamatsu. Ex.1006 at 4; *see supra* Section X.D.1.ii.

1119. Accordingly, Schima in view of Akamatsu-1999 discloses that "*the **heart assist pump device*** ("pump," Ex.1005) *is a catheter device*."

13. Motivation to Combine Schima with Akamatsu-1999

1120. It would have been obvious to use Schima's pump in the configuration described by Akamatsu-1999 (i.e., "*an inflow tube…insertable into a ventricle of the heart*") with an *external control unit* disclosed in Akamatsu-1999 for the reasons explained below (hereinafter the Schima/Akamatsu combination). The Akamatsu-1999 configuration ("*an inflow tube…insertable into a ventricle of the heart*")

1121. Schima is silent regarding implanting its pump in the body. However, it would have been readily apparent to a POSITA for the reasons below that Schima's pump would be implanted in the same way as Akamatsu's T-ILVAS device—Schima's "inlet 13" of the pump would *insertable into a ventricle of the heart* to collect blood from the left ventricle.

1122. Akamatsu-1999 and Schima are analogous art to the 356 Patent for several reasons. First, Akamatsu-1999 and Schima are both directed toward the **same field of endeavor** of the 077 Patent—"to assist the performance of a heart with at least one pump that is formed as a rotary pump and driven via magneto coupling." Ex.1001, Abstract; 2:52-62 ("The embodiment to assist the performance of a heart according to the invention"). Both Akamatsu-1999 and Schima are within this same field of endeavor. Ex.1006, at 3 ("a [r]otary blood pumps, such as…the centrifugal

pump, are being developed worldwide as implantable ventricular assist systems (VAS)"); Ex.1008, at [0001] ("The present invention relates to a rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing.").

1123. Second, Akamatsu-1999 and Schima are **reasonably pertinent to a problem** described by the 077 Patent: reducing mechanical stress on the blood during pumping. *See, e.g.*, Ex.1001, 2:20-24 ("A fluid flow which is improved by the pump is to be developed in a way in which the mechanical stress of highly sensitive fluids, such as blood for example, can be kept as low as possible and nevertheless the corresponding improvement to circulation can be ensured at desired locations."). Both Akamatsu-1999 and Schima aim to address this problem. Ex.1006, at 8 ("all of these pumps are subject to mechanical wear. Among these, the use of a magnetic suspension system has been one of the most promising approaches to obtain mechanical reliability as well as nonthrombogenicity of a rotary blood pump."); Ex.1005, [0002], [0009] ("The present invention relates to a rotary pump for moving blood and other shear-sensitive liquids with a rotor journaled hydraulically and, if necessary, magnetically in a housing.").

1124. It would have also been obvious to combine Schima and Akamatsu-1999 by using Schima's pump in the configuration described in Akamatsu-1999

because to do so would have been the **arrangement of old elements.** In fact, Schima already discloses its pump design would be suitable for use with the arrangement of old elements taught by Akamatsu. For example, Schima states:

> Akamatsu et al (see e.g. *Artificial Organs* 1997, Vol. 21, No. 7, pp. 645-638) proposes a pump where the rotor of a centrifugal pump is driven from one side by a standard motor and is stabilized by a controlled electromagnet. This pump above all is of complex construction and there is a small gap between the rotor and the housing for proper electrical operation
>
> …
>
> The present invention therefore has the object of overcoming these disadvantages. Mechanical depositions, dead-water zones or zones of reduced flow velocity and small gaps are to be avoided. The number of parts should be small and the construction simple.

1125. Ex.1005 at [0004]. Schima cites to a 1997 article by Akamatsu et al. (Ex 1017), but this is substantively the same device I describe above in connection with Akamatsu-1999 (Ex.1007). Thus, Schima identified some "disadvantages" with the Akamatsu design, but none of these disadvantages relate to Akamatsu's implantation of "*an inflow tube…insertable into a ventricle of the heart*" nor use of an "*external control unit*." Instead, Schima teaches that its pump could be used to

"overcome" "dead-water zones…and small gaps" identified with Akamatsu configuration, but the Schima pump could otherwise be implanted and controlled in the same way as the Akamatsu configuration.

1126. This configuration would have merely required arranging Schima's "inlet 13" as taught by the configuration of Akamatsu. For example, the "totally implantable left ventricular assist system (T-ILVAS)" described in Akamatsu-1999 includes an "inlet port" or "inflow conduit," which was "inserted into the left ventricle through a cuff sutured to the left ventricular apex ['*insertable into a ventricle of the heart*']." Ex.1006 at 4. Figure 1 (annotated) illustrates the T-ILVAS, including the centrifugal pump (**blue**) delivered to a heart (**red**) such that the inflow conduit (**green**) of the T-ILVAS is "*insertable into a ventricle of the heart*:"

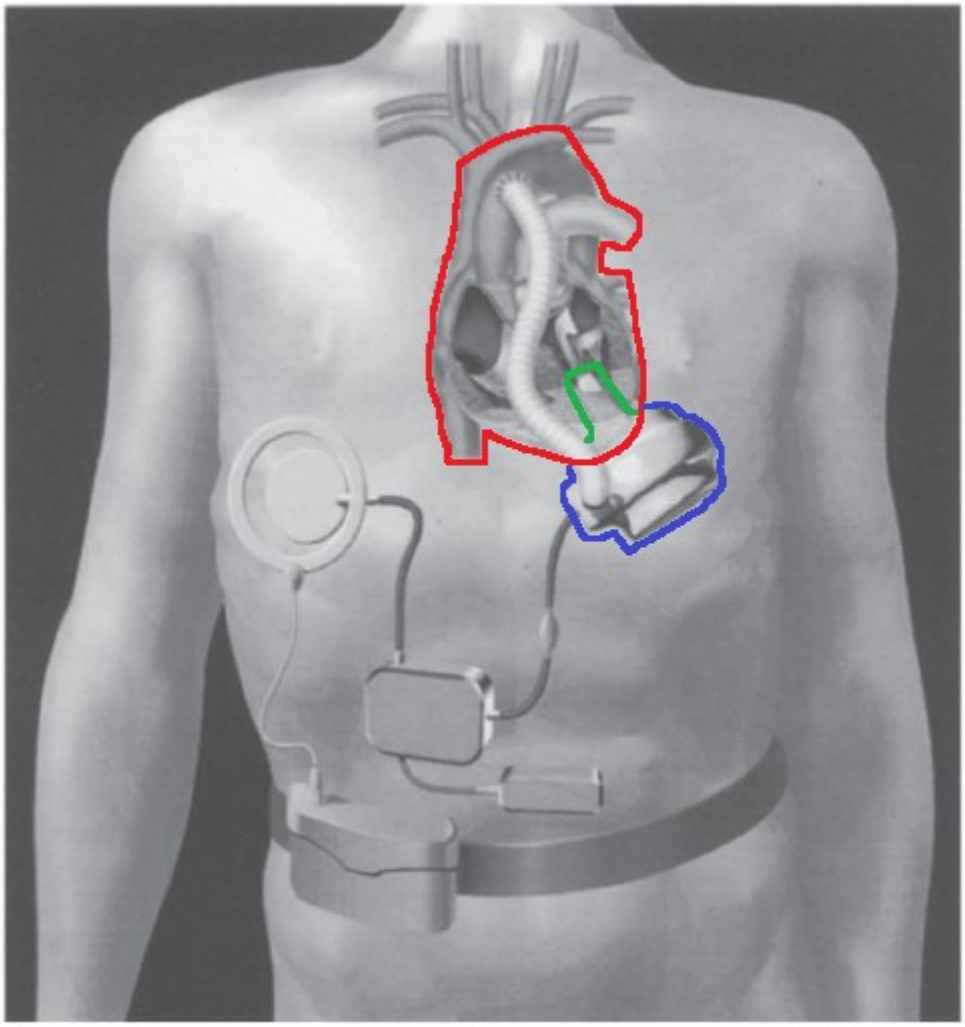


Fig. 1. Schematic illustration of the Terumo Implantable Left Ventricular Assist System (T-ILVAS)

Ex.1006, Fig. 1 (annotated). Thus, the Schima pump would be placed in the configuration as taught by Akamatsu (i.e., delivering Schima's "inlet 13" so that it *is insertable into a ventricle of the heart* in the same way as the Akamatsu-1999 inlet) with the pump performing the same function it has been known to perform (allow blood to flow from the heart through the *inflow tube toward the magnetically*

driven rotor) and yielding no more than one would expect from such an arrangement (*assisting the blood circulation of a heart*) as Schima demonstrates. Ex.1005, at [0009], [0010].

1127. Such a combination would have **yielded predicable results**. A POSITA could have combined Schima's improved pump design with Akamatsu-1999's described configuration where the inlet tube is inserted in the left ventricle using known methods, and such a method would merely perform the same function—assisting with blood flow, which is entirely predictable.

1128. A POSITA would have been **motivated to combine** Schima and Akamatsu-1999 so as to use Schima's pump and corresponding rotor design in the configuration shown in Akamatsu where the device is delivered to a heart for at least the reasons specifically discussed in Schima—the "[Akamatsu] pump above all is of complex construction and there is a small gap between the rotor and the housing" and those disadvantages can be "overcome[e]" by the rotor design of Schima's pump. Ex.1008, [0004], [0009] – [0010]. Thus, as Schima teaches, its pump would offer an advantageous design compared to the Akamatsu-1999 device because "[t]he number of parts [is] small and the construction simple," while being used to pump blood in the same way described in Akamatsu-1999. Ex.1008, [0009]. And because Schima did not identify any disadvantages with the Akamatsu-1999 configuration

as implanted in the body, a POSITA would have been motivated to implant the Schima pump using the Akamatsu-1999 configuration.

1129. Further, a POSITA would have had a **reasonable expectation of success** that the Schima/Akamatsu-1999 combination could deliver a pump to the left ventricle of a heart to improve blood flow to the aorta, because this design was well known and commonly used in the prior art. For example, Wampler-169 also employed a similar configuration as Akamatsu-1999 and reported that "[g]ood anatomic compatibility is possible since the [Wampler] pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm," so that when placed at the cardiac apex, an inlet tube and is placed into the apex of the left ventricle and an outlet to the aorta. *Id*. at [0075] - [0076]; Fig 5. Indeed, these third-generation type devices could be "implanted with routine surgical techniques via left ventricular apical cannulation and anastomosis to the descending aorta" leading to the "successful performance" of the pump in the animal studies. Ex.1007 at 403, 405. Thus, the implantation method for using a pump to improve blood flow described in Akamatsu-1999 was well-known at the time and a POSITA would have had a reasonable expectation of success in implanting Schima's pump according to Akamatsu's teaching. As such, it would also have been straightforward for a POSITA to implant Schima's pump according to Akamatsu-1999's teaching by

inserting the inlet into the left ventricle of the heart and directing the outlet to the aorta and that such a system would work.

a. The Akamatsu-1999 *external control unit*

1130. Schima is silent regarding how its "electric motor" is operated and controlled along with the destination of the signals sent by its sensors ("position sensors"). It would have been obvious to combine Schima and Akamatsu-1999 by using an *external control unit* as described in Akamatsu-1999 to control the operation of Schima's pump and to "*one or more sensors configured to deliver feedback signals to the external control unit*," such as Schima's "position sensors."

1131. As an initial matter, Akamatsu-1999 discloses different pumps that use either an internal or an external control unit. The "Model I" and "Model II" pumps used a controller *exterior* to the body while future development plans for a "Model III" pump involved "an implantable controller." Ex.1006 at 4, 7 ("For the next phase, we have developed the Model III system, consisting of a prototype MSCP with a sensorless motor and dual electric wires and an implantable controller …"). For instance, Akamatsu-1999 further discloses that during testing of the Model 1 and Model II "[t]he pump was percutaneously driven," i.e., via an external electric wire inserted through the skin. Ex.1006 at 4, 5. Figure 1 (annotated) of Akamatsu-1999

illustrates the connection of the external controller (**lime green**) to the centrifugal pump (**blue**):

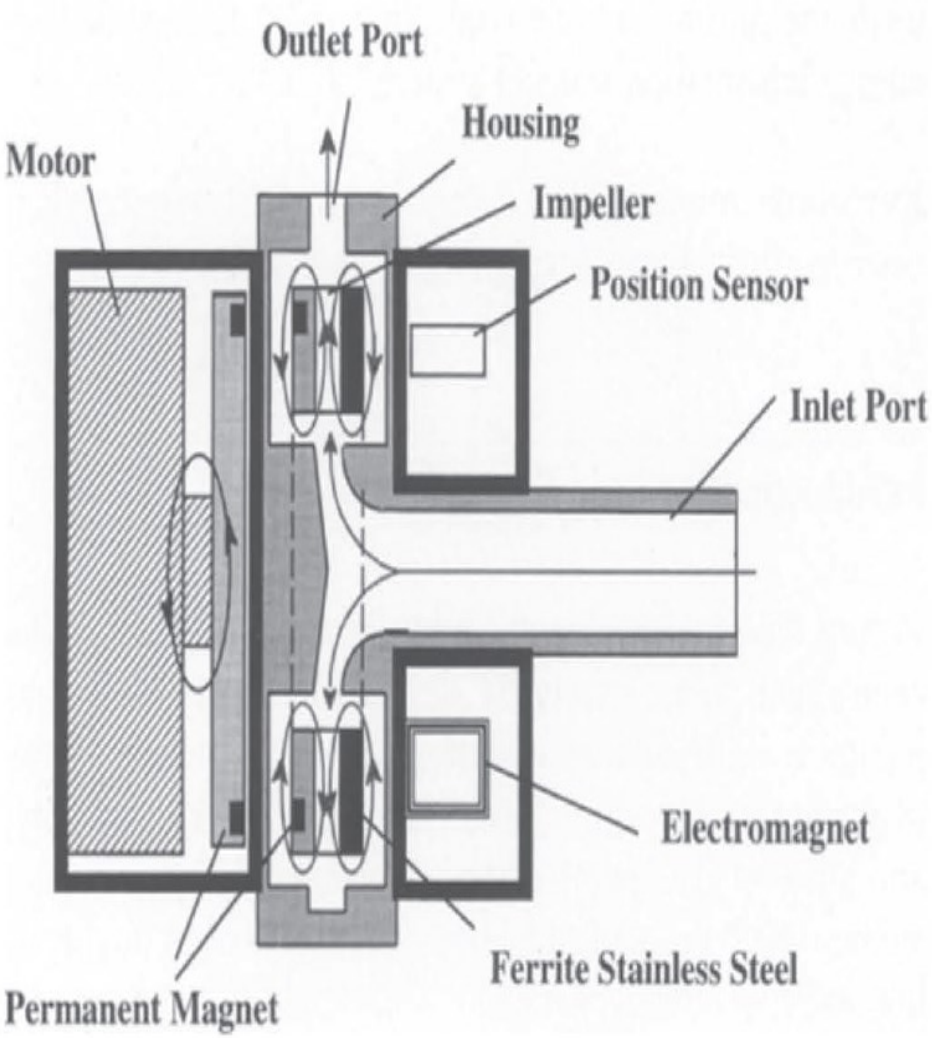


Fig. 2. Schematic cross section of the MSCP

Ex.1006, Fig. 1 (annotated). Thus, the "controller" disclosed in Akamatsu-1999 is an ***external control unit*** as recited in Claim 1.

1132. Using Akamatsu-1999's *external control unit* with the Schima pump would have been obvious, because, as explained above, Akamatsu-1999 and Schima are both directed toward the **same field of endeavor** of the 077 Patent and are **reasonably pertinent to a problem** described by the 077 Patent.

1133. Further, using an *external control unit* as described in Akamatsu-1999 to control the operation of Schima's pump would have merely been the **arrangement of old elements**.

1134. Both Schima and Akamatsu-1999 disclose the use of "position sensors" (i.e., "*one or more sensors*"). Ex.1005 at [0017] ("The position (running characteristic) of the rotor can for example be determined by appropriate position sensors"); Ex.1006 at 4 ("position sensors…maintain the impeller free-floating at the center of the pump housing"). Although Schima's specification describes the "position sensors…42" as shown in FIG. 4, Schima's claims cover an embodiment where "position sensors" are used in connection with the magneto coupling drive described in connection with FIG. 2. For example, claim 13 is a dependent claim that further requires "position sensors"—"[t]he pump according to one of claims 1 to 12, characterized in that in addition to the drive….additional sensors (42) are provided for determining the exact position of the rotor." Ex.1005, claim 13. Claim 11 claims a pump "characterized in that the magnetic drive is formed by a disk rotor,

a stator (38) being provided with a rotating disk (24) with imbedded magnets (10) or multiple magnetized regions," which is the same embodiment described in connection with FIG. 2 that uses magneto coupling drive. Because claim 13 depends from claim 11, Schima claims an embodiment where "position sensors" are used in connection with magneto coupling. Thus, both Akamatsu and Schima disclose the use of position sensors in connection with magneto coupling drive.

1135. In addition to Schima and Akamatsu-1999 both disclosing position sensors, Akamatsu-1999 also discloses the use of a "controller" (i.e., "*external control unit*") connected to the motor and the "the intra-housing connectors" by an "electric wire." Ex.1006 at 4 (describing that "an implantable controller" would be featured in future Model III devices but that Model I and II devices used external controllers), at 5 ("The pump was percutaneously driven"), Figs. 1-3. In addition, "[a]ortic pressure and pump flow rate were continuously measured throughout the experiments." Ex.1006 at 4, 5. Thus, Schima/Akamatsu combination would have used the same arrangement of elements between controller and sensor—connecting the Akamatsu-1999 "controller" (i.e., "*external control unit*") to the Schima pump and its "position sensors" (i.e., "*one or more sensors*") using an electric wire as taught by Akamatsu-1999.

1136. Further, a POSITA would have known that using this arrangement of old elements—the Akamatsu-1999 "controller" (i.e., "*external control unit*") to control the operation of Schima's pump to receive "*feedback signals*" and to "*regulat[e] operation*" of the "electric motor" in Schima's pump—would not have altered how Schima's pump works. Rather, the speed of the "electric motor 26" would necessarily be controlled by a user in some way in order to operate the pump properly. Ex.1005 at [0013], [0017]. Incorporating a "controller" with Schima's pump so that the pump is "percutaneously driven," i.e., via an electric wire through the skin, as described in Akamatsu-1999 would therefore be an obvious and easy to implement design choice that would have required merely using a known external "controller" in a known way to receive feedback signals from known "position sensors" and control the speed of an electric motor. Ex.1006 at 4, 5.

1137. Thus, this arrangement of old elements would have performed the same function they had been known to perform. The Akamatsu-1999 controller (i.e., "*external control unit*") allowed "*to regulate operation of the second magnetic device.*" Ex.1006 at 4 ("The pump was operated at a fixed rotational speed."). The Schima "position sensors" (i.e., "*one or more sensors*") would have determined "[t]he position (running characteristic) of the rotor," which is the same function the

position sensors had in Akamatsu-1999 "to maintain the impeller free-floating at the center of the pump housing." Ex.1005 at [0017]; Ex.1006 at 4.

1138. Further, this arrangement of old elements also would have yielded no more than one would expect from such an arrangement. The Akamatsu-1999 controller (i.e., "*external control unit*") yielded the ability to "operate[] "the pump…at a fixed rotational speed, i.e., "r*egulate operation of the second magnetic device based upon a control value indicative of cardiac output*." Ex.1006 at 4 ("The pump was operated at a fixed rotational speed."). The Schima "position sensors" (i.e., "*one or more sensors*") yielded the ability to "*provid[e] feedback signals to the external control unit*." Ex.1005 at [0017] ("The position (running characteristic) of the rotor can for example be determined by appropriate position sensors.").

1139. Moreover, a POSITA would have been **motivated to combine** the external control unit as described in Akamatsu to control the operation of Schima's pump and *provid[e] feedback signals to the external control unit from one or more sensors*, because such a configuration was a routine and well-known way to control operation of a pump, as evidenced by pumps with sensors and external controllers like Akamatsu-1999 (Ex.1006 at 4), Wampler (Ex.1008 at [0070] ("it is contemplated that controller 59 and power supply 61 may be worn externally by the user …"); and Bourque 2001 (Ex.1007 at 403). For example, the Bourque 2001

external controller allows for "regulating operation" because it controls the pump speed (rpm) to be "gradually adjusted to maintain volume flow rates." Ex.1007 at 403. Further, A POSITA would have been motivated so feedback signals from Schima's position sensors could be received by a controller to determine the position of Schima's rotor in order to properly control the speed of the "electric motor 26" which drives "rotating disk 24 with magnets 10." Ex.1005, [0013].

1140. Such a combination would have **yielded predicable results** using *one or more sensors* to provide *feedback signals to an external control unit* was well known in the field of heart assist pumps at the time of the invention. A POSITA could have combined Akamatsu-1999's "*external control unit*" with Schima's pump design using known methods, such as by connecting an "electric wire" to the pump "percutaneously" as described in Akamatsu-1999, and such a method would merely perform the same function—"*regulating operation*" and allow for "*providing feedback signals*," and these known methods were entirely predictable. *See* Akamatsu-1999, (Ex.1006 at 5 ("The pump was percutaneously driven.")); Wampler (Ex.1008 at [0070] ("a brushless rotor motor 53…[is] interconnected by means of percutaneous wires to a controller 59")); Bourque 2001 (Ex.1007 at 401, 405 ("The pumps…had percutaneous leads" and "an electronic cable to be exteriorized percutaneously")). While Akamatsu-1999 uses position sensors for a purpose not

needed in Schima, the results would have predictably been the same to provide the position and distance of the rotor from the housing to the controller in order regulate the speed of the motor so as to maintain contact-free rotation as described in Schima.

1141. A POSITA would have had a **reasonable expectation of success** because the use of external "controllers" in the field of heart assist pump devices was well known. For example, Bourque-2001 describes that in the *in vivo* testing of the HeartMate III, "electronics for power and control of the LVAD and for data acquisition resided on a shelf" and the test subjects were "continuously monitored for…certain parameters such as arterial pressure, pump and pulmonary artery volume flow rates, pump speed, and blood chemistry (including plasma free hemoglobin) were periodically recorded." Ex.1007 at 403. Likewise, Wampler-169 describes a rotary blood pump that includes a "controller 59" that "may include circuitry as simple as variable voltage or current control, manually adjusted or programed to determine the running rate of [the] pump" and may also "have interactive and automatic capabilities." Ex.1008, [0071]. For example, Wampler's "controller 59" may be "interconnected to sensors…to tailor operation of the pump to the user's physical activity and condition." Ex.1008, [0071]. Thus, implementing the combination would have been straightforward and well within the ordinary skillset of a POSITA at the time.

1142. Moreover, using Akamatsu's controller (i.e., "*external control unit*") with Schima's pump design would have been **obvious to try**. At the time of the claimed invention, it was within the general knowledge of a POSITA that the location of an LVAD's controller presented a finite number (i.e., two) options—a controller could be external or implanted (i.e., internal). Both techniques were well-known—in fact, Akamatsu-1999 discloses a Model III pump with inclusion of "an implantable controller" and a Model II pump using an external controller. Ex.1006 at 7 ("For the next phase, we have developed the Model III system, consisting of a prototype MSCP with a sensorless motor and dual electric wires and an implantable controller …"). In using an external controller, a POSITA would have had a reasonable expectation of success in view of the numerous other similar devices that also employed an external controller. *See* Ex.1006 at 7; Ex.1007 at 203 ("control of the LVAD…resided on a shelf"); Ex.1008 at [0070] ("it is contemplated that controller 59 and power supply 61 may be worn externally by the user …").

XI. CONCLUSION

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1101 of Title 18 of the United States Code.

Dated: Friday, November 22, 2024
At: Aarhus, Denmark

Peter Crosby

Peter Crosby